de: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS-3326-F]

RIN 0938-AT47

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories

AGENCY: Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule updates the Clinical Laboratory Improvement Amendments of 1988 (CLIA) fees and clarifies the CLIA fee regulations. This final rule implements a process for sustainable funding for the CLIA program through a biennial two-part increase of CLIA fees. We are finalizing the incorporation of limited/specific laboratory fees, including fees for follow-up surveys, substantiated complaint surveys, and revised certificates. We are also finalizing the distribution of the administrative overhead costs of test complexity determination for waived tests and test systems with a nominal increase in Certificate of Waiver (CoW) fees. In addition, we are finalizing the clarification of the methodology used to determine program compliance fees. This final rule ensures the continuing quality and safety of laboratory testing for the public. This final rule also amends histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes. In addition, this final rule amends the provisions governing alternative sanctions (including civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite State monitoring) to allow for the imposition of such sanctions on CoW laboratories.

DATES: These regulations are effective January 27, 2024, except for instruction 3, amending § 493.2; instructions 14 through 19, amending §§ 493.945, 493.1273, 493.1274, 493.1278, 493.1359, and 493.1405; instruction 20 removing § 493.1406; instructions 21 through 30, amending §§ 493.1407, 493.1411, 493.1417, 493.1423, 493.1443, 493.1445, 493.1449, 493.1451, 493.1455, and 493.1461; instruction 31 removing § 493.1462; and instructions 32 through 36, amending §§ 493.1463, 493.1469, 493.1483, 493.1483, 493.1489, and 493.1491, which are effective December 28, 2024.

FOR FURTHER INFORMATION CONTACT: Penny Keller, CMS, (410) 786-2035; or Heather Stang, CDC, (404) 498–2769.

SUPPLEMENTARY INFORMATION:

Executive Summary

A. Purpose

This final rule clarifies and updates CLIA regulations that protect the health and safety of laboratory consumers and address the financial stability of the CLIA program. Specifically, the final rule: (1) adjusts laboratory fees to provide sustainable funding for the user-fee-funded CLIA program; (2) revises certain requirements for both the histocompatibility test specialty as well as personnel qualifications and responsibilities for CLIA laboratories; and (3) provides additional discretion to CMS by allowing it to impose alternative sanctions against non-compliant Certificate of Waiver laboratories, rather than being limited only to imposing principal sanctions of revocation, suspension or limitation of a laboratory's CLIA certificate.

B. Summary of the Major Provisions

1. Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578), which revised in its entirety section 353 of the Public Health Service Act (PHSA). Section 353(m) of the PHSA requires the Secretary to impose two separate types of fees: "certificate fees" and "additional fees." Certificate fees are

imposed for the issuance and renewal of certificates and must be sufficient to cover the general costs of administering the CLIA program, including evaluating and monitoring approved proficiency testing (PT) programs and accrediting bodies and implementing and monitoring compliance with program requirements. Additional fees are imposed for inspections of nonaccredited laboratories and for the cost of evaluating accredited laboratories to determine overall if an accreditation organization's standards and inspection process are equivalent to the CLIA program. These evaluations are referred to as validation inspections. The additional fees must be sufficient to cover, among other things, the cost of carrying out such inspections. Certificate and additional fees vary by group or classification of laboratory, based on such considerations as the Secretary determines relevant, which may include the total test volume and scope of the testing being performed by the laboratories, and only a nominal fee may be required for the issuance and renewal of Certificates of Waiver (CoWs).

We issued a notice with comment period in the December 31, 2018 **Federal Register** (83 FR 67723 through 67728) [1] (hereinafter referred to as the December 31, 2018 notice). The December 31, 2018 notice increased fees for laboratories certified under CLIA. The December 31, 2018 notice increased CLIA fees by 20 percent to help ensure the CLIA program could continue to be self-sustaining, as required by law. The 2018 increase was intended to give CMS time to propose a process through rulemaking to allow for ongoing changes to the CLIA fees. Despite that increase, the level of carryover funding available to cover program expenses is projected to decline continuously. As such, the CLIA program will not be self-supporting by the end of FY 2023 without an additional fee increase. The changes finalized in this rule will result in a continuous level of funding that increases as the obligations to the CLIA program increase and keep the program adequately funded over time.

[1] See Medicare Program: Clinical Laboratory Improvement amendments of 1988 (CLIA) Fees; 83 FR 67723; *https://www.federalregister.gov/documents/2018/12/31/2018-28359/medicare-program-clinical-laboratory-improvement-amendments-of-1988-clia-fees*.

On July 7, 2022, we published a proposed rule (87 FR 44896)[2] (hereinafter referred to as the July 2022 proposed rule) that would make changes to the methodology for determining the amount of the CLIA fees as described in the February 28, 1992 final rule with comment period (57 FR 7002) (hereinafter referred to as the February 1992 final rule) and codified in 42 CFR part 493, subpart F – General Administration. The fees for the CoW, Certificate for Provider-performed Microscopy (PPM) Procedures, and the provisional certificate that we refer to as the Certificate of Registration (CoR) were based on the cost of issuing the certificates. The Certificate of Accreditation (CoA) and Certificate of Compliance (CoC) fees were based on the annual test volume and scope of testing that separated the laboratories into schedules or groups of laboratories. We generally proposed, and are finalizing in this rule, to continue basing these fees on either the costs of issuing the certificates (CoW, CoR, and PPM) or annual test volume and scope of testing (CoA and CoC). However, we are now including in this final rule additional government costs that were not accounted for in the calculation method outlined in the February 1992 final rule. As one such change, we proposed to allocate, directly from the CoW fees, the administrative overhead costs of the Food and Drug Administration (FDA) process to categorize clinical laboratory tests as waived as described in the memorandum of understanding (MOU) between CMS and FDA (IA19-23). In addition, we proposed to implement certificate fees for the issuance of replacement and revised certificates. Thousands of replacement and revised certificates are generated and mailed annually. We believe this additional certificate fee will encourage laboratories to better manage their certificates, provide accurate information when applying for or updating a CLIA certificate, and cover the costs of producing duplicate or revised documents.

[2] *https://www.federalregister.gov/documents/2022/07/26/2022-15300/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and.* The public comment period was extended and closed on September 26, 2022 (87 FR 52712). *https://www.federalregister.gov/documents/2022/08/29/2022-18558/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and*.

The February 1992 final rule also stated at § 493.645(b)(1) that laboratories issued a CoA would be assessed a fee to cover the cost of evaluating the individual laboratories to determine whether an accreditation program's standards and inspection policies are equivalent to the Federal program. We proposed at the new § 493.645(a)(1) to clarify that all accredited laboratories share in the validation inspections cost. Under § 493.645(b)(1), the accredited laboratories currently pay a fee even though HHS inspects only 5 percent of them annually. The fee is 5 percent of what the inspection cost of an equivalent nonaccredited CoC laboratory would pay based on the test volume and scope (that is, the schedule or group) of the laboratories.

In the February 1992 final rule, the inspection fees for laboratories holding a CoC were based on estimates of the length of time required to perform a laboratory survey in the different schedules multiplied by the estimated hourly rate of three different entities, the State agency, contracted surveyors, and Federal surveyors, that perform surveys. Of these three entities, an hourly rate was established solely for the State agencies, as any contracted surveyors' salaries are paid by their contractual amount. The Federal surveyors perform their surveys in conjunction with non-survey work plus actual costs for travel to those surveys. Given this diversity of costs, it is not feasible to determine a Federal hourly rate for just the survey activities. In the July 2022 proposed rule, we proposed to cease using the hourly rate outlined in current regulations as the basis for determining compliance inspection fees for laboratories holding a CoC and replace it with the methodology proposed in the proposed rule, and which we are finalizing in this final rule. We proposed to keep inspection fees separated by the schedules as previously determined.

The additional fees allowed for in section 353(m) of the PHSA are fees for determining compliance with the CLIA regulations. Some of these fees were previously included in subpart F but were not implemented due to technical limitations. However, we stated in the proposed rule that a new data system that can implement these requirements is under development. Therefore, as discussed further in this final rule, we are finalizing the implementation of additional fees as outlined in the February 1992 final rule, to be effective 30 days after the publication of the final

rule, although collection may not begin until the new data system is implemented. We believe the collection of these additional fees will help bridge the shortfall between program expenditures and collections as discussed in section I.A.1.a. of this final rule.

The February 1992 final rule provisions codified at 42 CFR part 493, subpart F – General Administration were numbered too close together to allow new provisions or the separation of existing provisions, for clarification, to stay in numerical order. Therefore, we proposed to redesignate and renumber some provisions so that the flow of this section is easier to follow. For example, we proposed to redesignate current § 493.646 as new § 493.655 to maintain thematic order in that § 493.655, which outlines the payment of fees, is better placed after the provisions discussing the different types of fees. Each such change, including this example, is explained in full at its designated provision within section II. of this final rule.

Upon the final rule effective date, which will be 30 days following publication, we proposed implementing fee increases as described previously in this rule. Using the more recent data available for this final rule, we expect the fee increase to be larger than subsequent fee increases. The fee increase includes an across-the-board increase of 18 percent and an inflation factor (CPI-U) of 1.049598. We utilized the CPI-U factors promulgated by OMB as part of their economic assumptions for budgetary estimates. To calculate the 4.9598 percent compound factor for the 2-year increase, we multiplied together factors for each of the 2 years as follows:

- Factor Year 1 (Budgeted Rate for Fiscal Year (FY) 2024) = 1.026
- Factor Year 2 (Budgeted Rate for FY 2025) = 1.023

The compounded factor = 1.026 x 1.023 = 1.049598

The 18 percent across-the-board (ATB) increase was determined as the amount that, including newly charged fees and inflation, is the difference necessary to fund total annual projected program obligations and allow for the gradual accumulation of 6 months' worth of obligations as an operating margin at the start of the year. We have calculated that the one-time 18 percent across-the-board increase would generate approximately 12.1 million dollars annually

while the inflation factor would generate approximately 4.6 million dollars. Based on the more recent data available for this final rule, the other proposed fees would generate approximately 7.7 million dollars for a total of approximately 24.4 million dollars per year.

We believe this will stabilize the CLIA program and allow us to use the inflation factor for future biennial increases. Should future across-the-board percentages be required, CMS will calculate them as stated in § 493.680(a). The revised certificate fee found at proposed § 493.639(a); the replacement certificate fee found at proposed § 493.639(b); the fees for the follow-up surveys, substantiated complaint surveys, and unsuccessful PT on CoC laboratories found at proposed § 493.643(d)(1) through (4); follow-up surveys on CoA laboratories found at proposed § 493.645(a)(2); and substantiated complaint surveys on CoW, PPM, or CoA laboratories found at proposed § 493.645(b) will be implemented on the effective date of the final rule. However, the collection of the fees is dependent on the new data system being online.

This final rule finalizes the proposed CLIA fee provisions with the modifications described in section II of this final rule.

2. CLIA Requirements for Histocompatibility

The CLIA regulations include requirements specific to certain laboratory specialties such as microbiology and subspecialties such as endocrinology. Histocompatibility is a type of laboratory testing performed on the tissue of different individuals to determine if one person can accept cells, tissue, or organs from another person. The CLIA regulatory requirements for the specialty of histocompatibility at § 493.1278, including the crossmatching requirements, address laboratory testing associated with organ transplantation and transfusion and testing on prospective donors and recipients. As of January 2023, 247 CLIA-certified laboratories perform testing in this specialty. The specialty of histocompatibility has not been updated since the February 1992 final rule (57 FR 7002). Many of the changes finalized in this rule will remove histocompatibility-specific requirements from § 493.1278 that we have determined are addressed by the general QC requirements at §§ 493.1230 through 493.1256 and 493.1281 through

493.1299. We believe that removing specific requirements for obsolete methods and practices and eliminating redundant requirements will decrease the burden on laboratories performing histocompatibility testing. We have heard from interested parties, particularly the transplantation community, that physical crossmatches are a barrier to modernized decision-making approaches on organ acceptability based on risk assessment.

For the crossmatching regulations that this final rule will amend, HHS requested input from the Clinical Laboratory Improvement Advisory Committee (CLIAC) on the acceptability and application of newer crossmatching techniques in lieu of physical crossmatching. At its November 2014 meeting, CLIAC made the following recommendations[3] for CMS to explore:

- Regulatory changes or guidance(s) that would allow virtual crossmatching to replace physical crossmatching as a pre-requisite for organ transplant.

- Appropriate criteria and decision algorithms, based on CLIAC's deliberation of the Virtual Crossmatch Workgroup's input, under which virtual crossmatching would be an appropriate substitute for physical crossmatching. The determination of appropriate criteria and decision algorithms should involve a process that includes an open comment period.

In the 2018 RFI (83 FR 1005 through 1006, 1008), we requested comments and information related to histocompatibility and crossmatching requirements that may have become outdated and requested suggestions for updating these requirements to align with current laboratory practice. The comments we received in response to the 2018 RFI recommended updating the current histocompatibility and crossmatching requirements to align with current laboratory practices. The CLIAC recommendations and the comments from the 2018 RFI informed the changes that we proposed in the July 2022 proposed rule, and which we are finalizing in this final rule.

This final rule finalizes the proposed histocompatibility provisions of the proposed rule with the modifications described in section III.A. of this final rule.

---

[3] *https://www.cdc.gov/cliac/docs/summary/cliac1114_summary.pdf.*

3. CLIA Requirements for Personnel

The CLIA regulations related to personnel requirements were updated with minor changes to the doctoral high complexity LD qualifications in the 2003 final rule (68 FR 3713, Jan. 24, 2003), but otherwise have remained unchanged since we published the February 1992 final rule with comment period (57 FR 7002). In the 2018 RFI (83 FR 1005 through 1006, 1008), we sought public comment and information related to CLIA personnel requirements in the following areas: nursing degrees; physical science degrees; personnel competency assessment (CA); personnel training and experience; and non-traditional degrees. These are areas that the CDC, CMS, interested parties, and State agency surveyors identified as relevant to our efforts to update the CLIA personnel requirements to better reflect current knowledge, changes in the academic context, and advancements in laboratory testing.

In response to our questions about nursing degrees, the majority of commenters did not concur that nursing degrees were equivalent to a biological or chemical sciences degree. However, some interested parties suggested nursing degrees could be used as a separate qualifying degree for nonwaived testing personnel (TP). In response to our questions about physical science degrees as well as non-traditional degrees, interested parties commented that a physical science degree was hard to define. In considering how to evaluate physical science and other non-traditional degrees, some commenters recommended that we evaluate coursework taken using a semester-hour educational algorithm to qualify individuals for CLIA personnel positions. In response to the questions about competency assessment (CA), many commenters stated that individuals with an applicable associate degree should be permitted to perform CA on moderate complexity TP. Some commenters stated that required training should depend on the complexity of the testing to be performed and that all nonwaived testing should require training related to the individual's laboratory responsibilities. Several commenters also stated that any required training and experience should be in a CLIA-certified laboratory. Many commenters agreed that all training and experience should be documented; many noted that documentation

from a former employer should be acceptable, assuming it provided specific details about the individual's job, training, and CA.

We also requested input from CLIAC for recommended changes to the CLIA personnel requirements found in subpart M – Personnel for Nonwaived Testing, §§ 493.1351 through 493.1495. CLIAC made 12 recommendations at the April 2019 meeting to improve CLIA personnel regulations, including: (1) making biological science degrees acceptable for laboratory personnel and considering candidates with other degree backgrounds based on coursework; (2) removing the degree in physical science from the CLIA regulations due to its broadness; and (3) requiring personnel to have training and experience in their areas of responsibility. Following this, CMS and CDC collaborated to develop a list of personnel regulation updates that we proposed in the July 2022 proposed rule.[4]

We are finalizing the proposed provisions for personnel with the modifications described in section III.B. in this final rule.

4. Alternative Sanctions for CoW Laboratories

As discussed in section III.C. of the proposed rule and this final rule, we proposed, and are finalizing, an amendment to § 493.1804(c)(1) to allow CMS to impose alternative sanctions on CoW laboratories, as appropriate. CoW laboratories are laboratories that only perform waived tests, that is, simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. For example, a urine dipstick pregnancy test is a waived test. The current regulations state that we do not impose alternative sanctions on CoW laboratories because those laboratories are not inspected for compliance with condition-level requirements (§ 493.1804(c)(1)). However, while not subject to the biennial routine surveys, CoW laboratories are surveyed as a result of a complaint, and based on the complaint survey, may be found to be out of compliance with a condition-level requirement. In the absence of alternative sanctions, our

[4] *https://www.federalregister.gov/documents/2022/07/26/2022-15300/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and*.

only recourse in cases of compliance issues found at CoW laboratories is to apply principal sanctions (that is, revocation, suspension, or limitation of the CLIA certificate). We believe the ability to levy alternative sanctions (that is, civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite State monitoring) on CoW laboratories helps CMS ensure appropriate sanctions are applied to CoW laboratories, as in the case of other certificate types (certificate of PPM, CoR, CoC, CoA).

In addition, we believe that this finalized change will reduce burden on CoW laboratories. The ability to impose alternative sanctions will be particularly useful in instances in which we find proficiency testing (PT) referral violations. PT is the testing of unknown samples sent to a laboratory by an HHS-approved PT program to check the laboratory's ability to determine the correct testing results. This final rule amends the CoW regulations at § 493.1804(c)(1) to allow for the application of alternative sanctions where warranted, in addition to or in lieu of principal sanctions.

We are finalizing the provisions for alternative sanctions for CoW laboratories as described in section III.C. in this final rule.

C. Summary of Costs and Benefits

TABLE 1: Costs and Benefits

Provision Description	Total Impact/Costs
CLIA Fee Regulations for CLIA laboratories	We estimate that the overall impact of updating the CLIA fees would be an increase of $24,371,183. The final rule impacts approximately 298,791 CLIA certified laboratories: Certificate of Waiver (CoW) = 235,175; Certificate for Provider-performed Microscopy (PPM) Procedures = 29,717; Certificate of Registration (CoR) = 2,891; Certificate of Compliance (CoC) = 17,694; Certificate of Accreditation (CoA) = 15,935. (Data from Casper 85s 02/07/2022). Although the effect of the changes will increase laboratory costs, implementation of these changes would be negligible in terms of workload for laboratories as these fee increases are operational and technical in nature and do not require additional time to be spent by laboratory employees.
Histocompatibility and Personnel Regulations for CLIA **laboratories**	We estimate that the overall impact of adding requirements for the changes in personnel, histocompatibility, and travel for LD on-site visits would range from $20,894,051 to $30,520,189 in the first year. The estimated costs included: (1) Laboratories updating policies and procedures related to personnel and histocompatibility, (2) Accrediting organizations and exempt States updating policies and procedures related to personnel, histocompatibility, and laboratory director site visit, (3) Travel for site visits-Driving, and 4) Travel for site visits-Flying. We estimate that the cost to laboratories, accrediting organizations, and exempt States to comply with the changes in the final rule would range between $20,894,051 and $30,520,189 in 2023 dollars for the first year and between $628,437 and $1,659,134 in subsequent years. Although the requirements will increase laboratory costs, the implementation of the final rule will streamline and simplify regulations, add flexibility in laboratory hiring practices, ensure that the LD is on-site at least twice per year, and align histocompatibility testing with current methods and practices.
Alternative Sanction	We believe this final rule will increase flexibility, decrease potential burden while moving those laboratories toward compliance, and have no added economic impact on CoW laboratories. As previously described, this regulatory change could decrease the burden for sanctions imposed for improper proficiency testing referral. Although we have no data indicating that principal sanctions have been imposed on CoW laboratories for this reason in the past, if it occurred in the future, the ability to impose alternative sanctions, if appropriate, would be less punitive and potentially decrease any quantifiable economic impact. At this time, we cannot quantify what that impact would be.

I. Background

A. Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578), which revised in its entirety section 353 of the Public Health Service Act (PHSA). Section 353(m) of the PHSA requires the Secretary to

impose two separate types of fees: “certificate fees” and “additional fees.” Certificate fees are imposed for the issuance and renewal of certificates and must be sufficient to cover the general costs of administering the CLIA program, including evaluating and monitoring approved proficiency testing (PT) programs and accrediting bodies and implementing and monitoring compliance with program requirements. Additional fees are imposed for inspections of nonaccredited laboratories and for the cost of evaluating accredited laboratories to determine overall if an accreditation organization’s standards and inspection process are equivalent to the CLIA program. These evaluations are referred to as validation inspections. The additional fees must be sufficient to cover, among other things, the cost of carrying out such inspections. Certificate and additional fees vary by group or classification of laboratory, based on such considerations as the Secretary determines relevant, which may include the total test volume and scope of the testing being performed by the laboratories, and only a nominal fee may be required for the issuance and renewal of Certificates of Waiver (CoWs).

In January 2018, we published the “Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988” (83 FR 1004). As part of the general solicitation for comments related to the CLIA fees, more than a few commenters noted that the CLIA compliance and additional fees have not been updated since 1997 and supported increasing the fees. Some of these commenters suggested that the CLIA fees be reviewed annually and updated as needed to cover the program costs of performing surveys.

Based on comments from the public on the Request for Information (RFI), we issued a notice with comment period in the December 31, 2018 **Federal Register** (83 FR 67723 through 67728) (hereinafter referred to as the December 31, 2018 notice). The December 31, 2018 notice increased fees for laboratories certified under CLIA. The December 31, 2018 notice increased CLIA fees by 20 percent to help ensure the CLIA program could continue to be self-sustaining, as required by law. The 2018 increase was intended to give CMS time to propose a process

through rulemaking to allow for ongoing changes to the CLIA fees. The changes finalized in this rule will result in a continuous level of funding that increases as the obligations to the CLIA program increase and keep the program adequately funded over time.

In September 2020, we released new tools to reduce burdensome paperwork and authorization delays for laboratories seeking CLIA certification. Laboratories now have the option to pay CLIA certification fees on the CMS CLIA program website. Online payments are processed overnight, which is substantially faster than hard-copy checks.[5]

In July 2022, we published a proposed rule (87 FR 44896)[6] (hereinafter referred to as the July 2022 proposed rule) that would make changes to the methodology for determining the amount of the CLIA fees as described in the February 28, 1992 final rule with comment period (57 FR 7002) (hereinafter referred to as the February 1992 final rule) and codified in 42 CFR part 493, subpart F – General Administration. The fees for the CoW, Certificate for Provider-performed Microscopy (PPM) Procedures, and the provisional certificate that we refer to as the Certificate of Registration (CoR) were based on the cost of issuing the certificates. The Certificate of Accreditation (CoA) and Certificate of Compliance (CoC) fees were based on the annual test volume and scope of testing that separated the laboratories into schedules or groups of laboratories. We generally proposed, and are finalizing in this rule, to continue basing these fees on either the costs of issuing the certificates (CoW, CoR, and PPM) or annual test volume and scope of testing (CoA and CoC). However, as described below, we are now including additional government costs that were not accounted for in the calculation method outlined in the February 1992 final rule.

As one such change, we proposed to allocate, directly from the CoW fees, the administrative overhead costs of the Food and Drug Administration (FDA) process to categorize

---

[5] *https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Index.*

[6] *https://www.federalregister.gov/documents/2022/07/26/2022-15300/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and.* The public comment period was extended and closed on September 26, 2022 (87 FR 52712). *https://www.federalregister.gov/documents/2022/08/29/2022-18558/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and*.

clinical laboratory tests as waived as described in the memorandum of understanding (MOU) between CMS and FDA (IA19-23). We believe this is appropriate because the functions of the FDA under the MOU are to provide administrative support to the CLIA program, such as by categorizing tests as waived.

In addition, we proposed to implement certificate fees for the issuance of replacement and revised certificates. We receive numerous requests daily for replacements of lost and misplaced certificates and for revised copies of certificates after demographic, laboratory director (LD), and/or specialty/subspecialty changes. As a result, thousands of replacement and revised certificates have been generated and mailed annually. We believe this additional certificate fee will encourage laboratories to better manage their certificates, provide accurate information when applying for or updating a CLIA certificate, and cover the costs of producing duplicate or revised documents.

The February 1992 final rule also stated at § 493.645(b)(1) that laboratories issued a CoA would be assessed a fee to cover the cost of evaluating the individual laboratories to determine whether an accreditation program's standards and inspection policies are equivalent to the Federal program. The February 1992 final rule explained that there would be a random sample of 5 percent of all accredited laboratories inspected by the Department of Health & Human Services (HHS), and the findings compared to the findings of the Accreditation Organizations (AOs). The February 1992 final rule stated that all accredited laboratories would share the cost of this activity and that the fees would be the same as for inspections by nonaccredited laboratories. We proposed new § 493.645(a)(1) to clarify that all accredited laboratories share in the validation inspections cost. Under § 493.645(b)(1), the accredited laboratories currently pay a fee even though HHS inspects only 5 percent of them annually. The fee is 5 percent of what the inspection cost of an equivalent nonaccredited CoC laboratory would pay based on the test volume and scope (that is, the schedule or group) of the laboratories.

In the February 1992 final rule, the inspection fees for laboratories holding a CoC were based on estimates of the length of time required to perform a laboratory survey in the different schedules multiplied by the estimated hourly rate of three different entities that perform surveys. As outlined in the February 1992 final rule, we believe this methodology was a starting point intended to allow the methodology to be adjusted as historical data and experience were gained. The three inspection entities mentioned in the February 1992 final rule were the State agency, contracted surveyors, and Federal surveyors. Of these three entities, an hourly rate was established solely for the State agencies, as any contracted surveyors' salaries are paid by their contractual amount. The Federal surveyors perform their surveys in conjunction with non-survey work plus actual costs for travel to those surveys. Given this diversity of costs, it is not feasible to determine a Federal hourly rate for just the survey activities.

Due to these difficulties, in July 2022 we proposed to cease using the hourly rate outlined in current regulations as the basis for determining compliance inspection fees for laboratories holding a CoC and replace it with the methodology proposed in the proposed rule, and which we are finalizing in this final rule. We proposed to keep inspection fees separated by the schedules as previously determined.

The additional fees allowed for in section 353(m) of the PHSA are fees for determining compliance with the CLIA regulations. Some of these fees were previously included in subpart F but were not implemented due to technical limitations. However, we stated in the proposed rule that a new data system that can implement these requirements is under development. While initially targeted for completion in October 2022, the new data system remains under development. Therefore, as discussed further in this final rule, we are finalizing the implementation of additional fees as outlined in the February 1992 final rule, to be effective 30 days after the publication of the final rule, although collection may not begin until the new data system is implemented. We believe the collection of these additional fees will help bridge the

shortfall between program expenditures and collections as discussed in section I.A.1.a. of this final rule.

The February 1992 final rule provisions codified at 42 CFR part 493, subpart F – General Administration were numbered too close together to allow new provisions or the separation of existing provisions, for clarification, to stay in numerical order. Therefore, we proposed to redesignate and renumber some provisions so that the flow of this section is easier to follow. For example, we proposed to redesignate current § 493.645(a) as § 493.649(a) and remove the current regulatory text at § 493.649. In addition, we proposed redesignating current § 493.646 as new § 493.655 to maintain thematic order in that § 493.655, which outlines the payment of fees, is better placed after the provisions discussing the different types of fees. Each such change, including this example, is explained in full at its designated provision within section II. of this final rule.

Upon the final rule effective date, which will be 30 days following publication, we proposed implementing fee increases as described previously in this rule. Using the more recent data available for this final rule, we expect the fee increase to be larger than subsequent fee increases. The fee increase includes an across-the-board increase of 18 percent and an inflation factor (CPI-U) of 1.049598. We utilized the CPI-U factors promulgated by OMB as part of their economic assumptions for budgetary estimates. To calculate the 4.9598 percent compound factor for the 2-year increase, we multiplied together factors for each of the 2 years as follows:

- Factor Year 1 (Budgeted Rate for Fiscal Year (FY) 2024) = 1.026
- Factor Year 2 (Budgeted Rate for FY 2025) = 1.023

The compounded factor = 1.026 x 1.023 = 1.049598

The 18 percent across-the-board (ATB) increase was determined as the amount that, including newly charged fees and inflation, is the difference necessary to fund total annual projected program obligations and allow for the gradual accumulation of 6 months' worth of obligations as an operating margin at the start of the year. We have calculated that the one-time

18 percent across-the-board increase would generate approximately 12.1 million dollars annually while the inflation factor would generate approximately 4.6 million dollars. Based on the more recent data available for this final rule, the other proposed fees would generate approximately 7.7 million dollars for a total of approximately 24.4 million dollars per year. These projections are summarized in Table 2.

TABLE 2: Projected FY 2024 Collections With the Fee Increases Implemented in this Final Rule

	FY 2024 Post Final Rule
Across the Board	$12.1 million
Inflation Factor (1.049)	$4.60 million
Other Fees	$7.7 million
Total	$24.4 million

We believe this will stabilize the CLIA program and allow us to use the inflation factor for future biennial increases. Should future across-the-board percentages be required, CMS will calculate them as stated in § 493.680(a). The revised certificate fee found at proposed § 493.639(a); the replacement certificate fee found at proposed § 493.639(b); fees for the follow-up surveys, substantiated complaint surveys, and unsuccessful PT on CoC laboratories found at proposed § 493.643(d)(1) through (4); follow-up surveys on CoA laboratories found at proposed § 493.645(a)(2); and substantiated complaint surveys on CoW, PPM, or CoA laboratories found at proposed § 493.645(b) will be implemented on the effective date of the final rule. However, the collection of the fees is dependent on the new data system being online.

1. CLIA Budget Process

In the proposed rule, Table 1 provided a summary of projected user fee collections, program obligations, and carryover balances from FY 2021 through the end of FY 2025. In Table 3 of this final rule, we have expanded the information as presented in Table 1 of the proposed rule to include actual figures for FYs 2019 through 2022 which show the effect the 20 percent increase in 2019 had on CLIA's finances and updated projections for FYs 2023 through FY 2026 reflecting updated estimates of program spending, user fee collections, carryover, and

inflation. Table 3 does not include any proposed or finalized fee increases. We are also including additional detail related to total CLIA obligations. Start of year carryover balances plus anticipated collections at current rates, net of sequester, equals budgetary resources available for obligation, or spending, in a given fiscal year. This amount, less projected program obligations, equals end-of-year carryover. The continued decrease in the projected end-of-year carryover shows that despite the 2019 increase, financial obligations for the CLIA program continue to significantly outpace user fee collections at current rates. This final rule will create sustainable funding in a few different ways.

TABLE 3: CMS Actual and Projected CLIA Obligations and Fee Collections Without Finalized Fee Increases

	FY 2019 Actual	FY 2020 Actual	FY 2021 Actual	FY 2022 Actual	FY 2023	FY 2024	FY 2025	FY 2026
Available Carryover (SOY)*	$35,801,852	$37,828,689	$37,971,994	$35,606,303	$36,705,507	$26,066,877	$13,434,912	($1,006,235)
New collections	$60,154,865	$63,969,709	$70,009,410	$72,694,131	$70,019,000	$70,019,000	$70,019,000	$70,019,000
Sequester	($3,729,602)	($3,774,213)	($3,990,536)	($4,143,565)	($3,991,096)	($3,991,096)	($3,991,096)	($3,991,096)
Available Budgetary Resources**	$92,227,115	$98,024,185	$103,990,868	$104,156,869	$102,733,631	$92,095,002	$79,616,370	$65,332,083
State Survey Costs	$21,672,324	$21,958,788	$22,988,860	$26,184,632	$28,726,380	$29,473,266	$30,151,151	$30,844,627
Other Operations Costs	$24,407,020	$20,936,453	$29,418,719	$26,082,439	$26,745,981	$27,441,377	$28,072,529	$28,718,197
Administration Costs	$18,149,927	$18,682,234	$19,619,008	$19,619,008	$21,194,393	$21,745,447	$22,245,592	$22,757,241
Total Obligations***	$64,229,272	$61,577,475	$72,026,587	$71,765,273	$76,666,754	$78,660,090	$80,469,272	$82,320,065
Carryover (EOY)*	$27,997,843	$36,446,710	$31,964,280	$32,391,596	$26,066,877	$13,434,912	($1,006,235)	($17,298,175)

*SOY = Start of Year; EOY = End of Year. SOY carryover amounts in fiscal years 2019 through 2022 include the effects of prior year adjustments.

** Budgetary resources mean amounts available to be obligated. In this instance, it means the sum of available carryover + new user fee collections less projected sequestration reductions.

*** Obligations as of fiscal year end. The figure for Total Obligations is the sum of State Survey Costs, Other Operations Costs and Costs of Administration.

a. Two-part Periodic Increase

As we explained in the July 2022 proposed rule, establishing a two-part periodic increase could be easily implemented and would provide an understandable calculation of fee increases. CMS will publish future fee increases in a notice in the **Federal Register**. CMS will not publish a notice in the **Federal Register** if no fee increases are required. Every 2 years, in preparation for the biennial fee increase, we will calculate the inflation adjustment using the Consumer Price Index for all Urban Consumers (CPI-U). At that time, CMS will look back over the previous 2 years and determine if the calculated CPI-U inflation adjustment will be sufficient to cover actual program obligations. If the total fee amounts, including any increase applied, do not match or exceed actual program obligations based on a review of the obligations of the previous 2 years, CMS will apply an additional across-the-board increase to each laboratory's fees by calculating the difference between the total fee amounts and actual program obligations. If CMS determines that the inflation adjustment is not enough to cover the program obligations, an additional across-the-board amount will be added to the adjustment to ensure that the fee increase is spread equally across all fees in a flat percentage amount, which will cover CLIA obligations. The adjusted fees will become part of the baseline for the next biennial increase. If the level of collections was found to be sufficient to cover program obligations, CMS will not implement a biennial inflation adjustment or an across-the-board fee increase. With any fee increase, the amount of the increase and a summary of CLIA obligations along with the calculations of the increase using the CPI-U and any determined shortfall will be published in a notice in the **Federal Register**.

Table 4 shows a representation of the change in national average laboratory fees for the two-part increase of 4.9598 percent over the current fees with a one-time 18 percent across the board increase at the time of implementation.

TABLE 4: Examples, Two-part Increase per Certificate Type *

National Average CoC compliance fee/CoA Validation Survey fee					CLIA Biennial Certificate fees					
Laboratory classification (schedule)	Current average		Example, One-Time 18% Across the board with Biennial Increase of 4.96%		Current average			Example, One-Time 18% Across the board with Biennial Increase of 4.96%		
	CoC	CoA	CoC	CoA	CoC/CoA	CoW	PPM	CoC/CoA	CoW***	PPM
LVA**	$360	$18	$446	$22	$180	-	-	$223	-	-
A	$1,192	$60	$1,477	$74	$180	-	-	$223	-	-
B	$1,591	$80	$1,970	$98	$180	-	-	$223	-	-
C	$1,988	$99	$2,463	$123	$516	-	-	$639	-	-
D	$2,336	$117	$2,894	$145	$528	-	-	$654	-	-
E	$2,684	$134	$3,325	$166	$780	-	-	$966	-	-
F	$3,032	$152	$3,755	$188	$1,320	-	-	$1,635	-	-
G	$3,380	$169	$4,187	$209	$1,860	-	-	$2,304	-	-
H	$3,728	$186	$4,618	$231	$2,448	-	-	$3,032	-	-
I	$4,076	$204	$5,049	$252	$7,464	-	-	$9,244	-	-
J	$4,408	$220	$5,459	$273	$9,528	-	-	$11,801	-	-
Not applicable	-	-	-	-	-	$180	$240	-	$248	$297

*Note: The Certificate of Registration (CoR) fee would increase from the $150 to $184.
**LVA “Schedule A, Low Volume”.
***CoW $248 includes $223 + $25 CoW one-time increase.

b. Collection of Other Authorized Fees

The CLIA regulations also authorize the collection of other fees; however, the program has historically not exercised its authority in collecting these fees due to technical difficulties. With the improvement in technology since 1992, we will be enforcing existing regulatory authority in the collection of these fees as well as clarifying circumstances when such fees are applicable. This final rule will implement collection of these other fees, which are laboratory specific and provide an incentive for laboratories to remain compliant with all provisions of the CLIA regulations.

The fees include:

- A fee for follow-up surveys to determine correction of the deficient practices found in either a CoC survey or a CoA validation survey;
- An addition of a specialties survey fee when it is necessary to determine compliance of testing in one or more additional specialties outside of the CoC survey cycle;
- A substantiated complaint survey fee;
- A fee for a desk review of unsuccessful PT performance;
- A fee for a replacement certificate when a laboratory loses or destroys a CLIA certificate and requests a replacement certificate; and
- A fee for issuing a revised certificate when the laboratory changes the laboratory director or other information found on a certificate and requests a new certificate to reflect the changes.

Table 5 projects the national average fees per incident. These fees were previously authorized in the February 1992 final rule but were not collected. We are now finalizing the collection of these additional fees. We totaled the number of follow-up surveys, substantiated complaints, and unsuccessful PT events and multiplied them by the national average number of hours recorded by the State survey agencies for these activities in FY2019. For follow-up surveys, substantiated complaints, and unsuccessful PT events we then multiplied that by the

national average unit cost, which is $108.78 in FY2023. The amounts for the revised certificates and replacement certificates are the fee amount as discussed in section II.C. of this final rule, specifically at § 493.639(a).

TABLE 5: Projection of other Authorized Fees per Certificate Type

Projected National Average Other Authorized fees					
Certificate type	**Follow-up surveys (including those for the addition of specialties)**	**Substantiated Complaint Surveys**	**Unsuccessful Proficiency Testing (PT) event**	**Replacement Certificates**	**Revised Certificates**
Certificate of Compliance (CoC)	$497	$2836	$780	$75	$150
Certificate of Accreditation (CoA)	$497	$7564	$780	$75	$95
Certificate of Registration (CoR)	$497	$4230	$780	$75	$150
Certificate of Waiver (CoW)	n/a	$2059	n/a	$75	$95
Certificate for Provider-performed Microscopy (PPM) Procedures	n/a	$3858	n/a	$75	$150

2. CoW Fee Increase

This final rule authorizes a fee increase for the CoW. A CoW laboratory is limited to performing tests categorized by FDA as waived, which are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or that the Secretary has determined pose no unreasonable risk of harm to the patient even if performed incorrectly. Some examples of waived tests include fingerstick tests for blood glucose or cholesterol. As part of our financial obligations to administer the CLIA program, we compensate FDA for its role in determining if tests and test systems meet criteria to be categorized as waived tests/test systems. This final rule implements a nominal increase for CoW fees which will offset program obligations to FDA for its role under the CMS–FDA MOU (IA19-23) in categorizing tests and test systems as waived. The obligation to CLIA, defined by the MOU and calculated against the number of CoW laboratories, is approximately $25 per

laboratory to cover the FDA obligation. The additional $25.00 will increase the current $180.00 biennial CoW fee to $205.00.

B. CLIA Requirements for Histocompatibility, Personnel, and Alternative Sanctions for CoW Laboratories

CLIA requires any laboratory that examines human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health, of human beings to be certified by the Secretary for the categories of examinations or procedures performed by the laboratory. The implementing regulations at 42 CFR part 493 specify the conditions and standards that must be met to achieve and maintain CLIA certification. These conditions and standards strengthen Federal oversight of clinical laboratories and help ensure the accuracy and reliability of patient test results.

CMS is always looking for ways to improve our programs and better serve our beneficiaries. Concerning laboratory oversight, HHS endeavors to improve consistency in the application of laboratory standards, coordination, collaboration, and communication in both routine and emergent situations, thereby further improving laboratory oversight and, ultimately, patient care. The regulations related to CLIA histocompatibility and personnel requirements have not been updated since 1992[7] and 2003,[8] and the regulations for CoW laboratory alternative sanctions have not been updated since 1992.[9] HHS believes it is time to update these regulations to reflect the current state of the American health care system and new advances in technology.

HHS sought expert advice to inform our decision-making on the regulatory updates finalized in this rule. We solicited advice on several topics addressed in this rule from the Clinical Laboratory Improvement Advisory Committee (CLIAC), the official Federal advisory

---

[7] See the "Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA)" final rule with comment period (57 FR 7002) that published in the February 28, 1992 **Federal Register** (hereinafter referred to as the "1992 final rule with comment period").

[8] See the "Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications" final rule (68 FR 3640) that published in the January 24, 2003 **Federal Register** (hereinafter referred to as the "2003 final rule").

[9] See the 1992 final rule with comment period.

committee charged with advising HHS regarding appropriate regulatory standards for ensuring accuracy, reliability, and timeliness of laboratory testing. On January 9, 2018, we also issued a Request for Information[10] (RFI) that solicited input from the public on issues related to CLIA personnel and histocompatibility requirements, and alternative sanctions for CoW laboratories. We received approximately 8,700 total comments in response to the 2018 RFI. The CLIAC recommendations and information received in response to the 2018 RFI helped us determine the policies that were proposed in the July 2022 proposed rule, for which we received 20,574 public comments. We considered the public comments received in determining the policies finalized in this final rule.

This final rule amends histocompatibility and personnel regulations to address obsolete regulations and update the regulations to incorporate changes in technology. This final rule also amends § 493.1804(c) to allow alternative sanctions to be imposed on CoW laboratories. We summarize and respond to the public comments on these proposals and summarize our final policies in section III of this final rule.

1. Histocompatibility

The CLIA regulations include requirements specific to certain laboratory specialties such as microbiology and subspecialties such as endocrinology. Histocompatibility is a type of laboratory testing performed on the tissue of different individuals to determine if one person can accept cells, tissue, or organs from another person. The CLIA regulatory requirements for the specialty of histocompatibility at § 493.1278, including the crossmatching requirements, address laboratory testing associated with organ transplantation and transfusion and testing on prospective donors and recipients. As of January 2023, 247 CLIA-certified laboratories perform testing in this specialty. The current specialty regulations were published in the 1992 final rule

[10] See the "Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)" RFI (83 FR 1004) that published in the January 9, 2018 **Federal Register** (hereinafter referred to as the "2018 RFI").

with comment period, and additional changes were made in the 2003 final rule. Specifically, the 2003 final rule changed the regulations to decrease the number of specialty/subspecialty-specific quality control (QC) regulations in instances where general QC requirements would apply. The specialty of histocompatibility has not yet been similarly updated. Many of the changes finalized in this rule will remove histocompatibility-specific requirements from § 493.1278 that we have determined are addressed by the general QC requirements at §§ 493.1230 through 493.1256 and 493.1281 through 493.1299. We believe that removing specific requirements for obsolete methods and practices and eliminating redundant requirements will decrease the burden on laboratories performing histocompatibility testing. We have heard from interested parties, particularly the transplantation community, that physical crossmatches are a barrier to modernized decision-making approaches on organ acceptability based on risk assessment.

For the crossmatching regulations that this final rule will amend, HHS requested input from CLIAC on the acceptability and application of newer crossmatching techniques in lieu of physical crossmatching. The CLIAC gathered information on the acceptability and application of newer crossmatching techniques for transplantation because there have been advances in the field of transplantation since 1992. These advances have made the physical crossmatch less significant in non-sensitized patients. The CLIAC stated that histocompatibility testing has advanced in technology overtime, from using cell-based assays to complex testing procedures such as molecular typing and solid-phase platforms for antibody detection, with improved accuracy and sensitivity. Significant changes have occurred in the clinical practice of transplantation (immunosuppression, desensitization practices), and improvements in anti-rejection therapies have led to improved outcomes and mitigation of risk due to human leukocyte antigen (HLA) antibodies. At its November 2014 meeting, CLIAC made the following recommendations[11] for CMS to explore:

[11] *https://www.cdc.gov/cliac/docs/summary/cliac1114_summary.pdf.*

- Regulatory changes or guidance(s) that would allow virtual crossmatching to replace physical crossmatching as a pre-requisite for organ transplant.

- Appropriate criteria and decision algorithms, based on CLIAC deliberation of the Virtual Crossmatch Workgroup's input, under which virtual crossmatching would be an appropriate substitute for physical crossmatching. The determination of appropriate criteria and decision algorithms should involve a process that includes an open comment period.

In the 2018 RFI (83 FR 1005 through 1006, 1008), we requested comments and information related to histocompatibility and crossmatching requirements that may have become outdated and requested suggestions for updating these requirements to align with current laboratory practice. The comments we received in response to the 2018 RFI recommended updating the current histocompatibility and crossmatching requirements to align with current laboratory practices. The CLIAC recommendations and the comments from the 2018 RFI informed the changes that we proposed in the July 2022 proposed rule, and which we are finalizing in this final rule, after consideration of comments received.

2. Personnel

The CLIA regulations related to personnel requirements were updated with minor changes to the doctoral high complexity LD qualifications in the 2003 final rule (68 FR 3713) but otherwise have remained unchanged since we published the February 1992 final rule with comment period (57 FR 7002). In the 2018 RFI (83 FR 1005 through 1006, 1008), we sought public comment and information related to CLIA personnel requirements in the following areas: nursing degrees; physical science degrees; personnel competency assessment (CA); personnel training and experience; and non-traditional degrees. As we explained in the 2018 RFI, these are areas that the CDC, CMS, interested parties, and State agency surveyors identified as relevant to our efforts to update the CLIA personnel requirements to better reflect current knowledge, changes in the academic context, and advancements in laboratory testing.

We received approximately 8,700 comments in response to the 2018 RFI. In response to our questions about nursing degrees, the majority of commenters did not concur that nursing degrees were equivalent to a biological or chemical sciences degree. However, some interested parties suggested nursing degrees could be used as a separate qualifying degree for nonwaived testing personnel (TP). In response to our questions about physical science degrees as well as non-traditional degrees, interested parties commented that a physical science degree was hard to define. In considering how to evaluate physical science and other non-traditional degrees, some commenters recommended that we evaluate coursework taken using a semester-hour educational algorithm to qualify individuals for CLIA personnel positions. If an individual has the appropriate coursework without the traditional chemical or biological degree, the individual's educational coursework should be considered when determining whether that individual meets the educational requirements under CLIA. In response to the questions about competency assessment (CA), many commenters stated that individuals with an applicable associate degree should be permitted to perform CA on moderate complexity TP. Some commenters stated that required training should depend on the complexity of the testing to be performed and that all nonwaived testing should require training related to the individual's laboratory responsibilities. Several commenters also stated that any required training and experience should be in a CLIA-certified laboratory. Many commenters agreed that all training and experience should be documented; many noted that documentation from a former employer should be acceptable, assuming it provided specific details about the individual's job, training, and CA.

In addition to the 2018 RFI, we requested input from CLIAC for recommended changes to the CLIA personnel requirements found in subpart M – Personnel for Nonwaived Testing, §§ 493.1351 through 493.1495. In response, CLIAC established a workgroup that included laboratory experts, representatives from accreditation organizations (AOs), and government. The CLIAC Personnel Regulations Workgroup provided information and data to CLIAC for their

deliberation in recommending to HHS to update the personnel regulations.[12] CLIAC made 12 recommendations at the April 2019 meeting to improve CLIA personnel regulations, including: (1) making biological science degrees acceptable for laboratory personnel and considering candidates with other degree backgrounds based on coursework; (2) removing the degree in physical science from the CLIA regulations due to its broadness; and (3) requiring personnel to have training and experience in their areas of responsibility.

After the April 2019 CLIAC meeting, CMS and CDC met to review and consider the recommendations along with the information provided in response to the 2018 RFI. The following CLIAC recommendations support proposals included in the July 2022 proposed rule:

- Coursework should be considered in meeting CLIA personnel requirements;
- Degree in physical science should be removed from CLIA regulations;
- All personnel should have appropriate training and experience;
- Remove the statement "possess qualifications that are equivalent to those required for such certification", as applicable;
- Laboratory experience should be clinical in nature;
- 20 credit hours of relevant continuing education should be required for all LDs except those certified by the American Board of Pathology, American Board of Osteopathic Pathology, and American Board of Dermatology;
- LDs should make at least two reasonably spaced onsite visits to the laboratories they direct annually. These visits should be documented;
- Modify CLIA requirements for technical consultants (TC) to include an associate degree and training and experience; and
- Modify the definition of mid-level practitioner to include registered nurse anesthetists and clinical nurse specialists.

[12] *https://www.cdc.gov/cliac/docs/summary/cliac0419_summary.pdf.*

Following this, CMS and CDC collaborated to develop a list of personnel regulation updates that we proposed in the July 2022 proposed rule.[13]

3. Alternative Sanctions for CoW Laboratories

As discussed in section III.C. of the proposed rule and this final rule, we proposed, and are finalizing, an amendment to § 493.1804(c)(1) to allow CMS to impose alternative sanctions on CoW laboratories, as appropriate. CoW laboratories are laboratories that only perform waived tests, that is, simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. For example, a urine dipstick pregnancy test is a waived test. The current regulations state that we do not impose alternative sanctions on CoW laboratories because those laboratories are not inspected for compliance with condition-level requirements (§ 493.1804(c)(1)). However, while not subject to the biennial routine surveys, CoW laboratories are surveyed as a result of a complaint, and based on the complaint survey, may be found to be out of compliance with a condition-level requirement. In the absence of alternative sanctions, our only recourse in cases of compliance issues found at CoW laboratories is to apply principal sanctions (that is, revocation, suspension, or limitation of the CLIA certificate). We believe the ability to levy alternative sanctions (that is, civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite State monitoring) on CoW laboratories helps CMS ensure appropriate sanctions are applied to CoW laboratories, as in the case of other certificate types (certificate of PPM, CoR, CoC, CoA).

In addition, we believe that this finalized change will reduce burden on CoW laboratories. The ability to impose alternative sanctions will be particularly useful in instances in which we find PT referral violations. PT is the testing of unknown samples sent to a laboratory by an HHS-approved PT program to check the laboratory's ability to determine the correct testing results. This final rule amends the CoW regulations at § 493.1804(c)(1) to allow for the

[13] *https://www.federalregister.gov/documents/2022/07/26/2022-15300/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and*.

application of alternative sanctions where warranted, in addition to or in lieu of principal sanctions.

We note that while the regulatory text at § 493.1804(c)(1) currently specifies that CMS will not impose alternative sanctions on laboratories that have CoWs because those laboratories are not inspected for compliance with condition-level requirements, this distinction is not required by the applicable statute at 42 U.S.C. 263a(h). Therefore, as discussed in section III.C. of this final rule, we proposed to remove, and are finalizing the removal of, the current parenthetical at § 493.1804(c), which states "(Except for a condition level deficiency under §§ 493.41 or 493.1100(a), CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not routinely inspected for compliance with condition-level requirements.)". We note that the language "Except for a condition level deficiency under §§ 493.41 or 493.1100(a)", which was inadvertently omitted from the discussion of this parenthetical in the July 2022 proposed rule, was added in the Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency interim final rule with comment period, published in the September 2, 2020, **Federal Register** (85 FR 54820). This language was only effective during the PHE for COVID-19 which ended on May 11, 2023. Consistent with the finalized amendment to remove the current parenthetical at § 493.1804(c), this language will also be deleted as of the effective date of this final rule.

In responses received from the 2018 RFI, commenters noted that alternative sanctions instead of principal sanctions should be an option to create parity for all certificate types, especially in cases of PT referral. Further, commenters also stated that CoW laboratories should be held to the same standards and level of compliance as those that perform moderate complexity and/or high complexity testing.

II. Provisions for CLIA Fees

This final rule will amend subpart F – General Administration in the CLIA regulations. This section provides an overview of the proposed revisions to the CLIA fee requirements established by the February 1992 final rule. We also summarize and respond to the public comments on the July 2022 proposed rule and state our final policies.

A. Definitions of "Replacement Certificate" and "Revised Certificate" (§ 493.2)

At § 493.2, we proposed to add definitions for "Replacement certificates" and "Revised certificates." After several years of experience and data analysis, it has been determined that the number of reissued certificates continues to be remarkable. Reissued certificates fall into two different categories: revised and replacement certificates. For further discussion please refer to section II.C. of this final rule. We proposed that these definitions be added to § 493.2 with the other definitions listed to allow clarity in the regulations where fees for replacement and revised certificates are being proposed.

We did not receive any public comments on the proposed definitions at § 493.2 of "replacement certificate" or "revised certificate" and are finalizing those definitions as proposed.

B. Changes to Certificate Fees (§ 493.638)

At § 493.638(a), we proposed to amend the regulatory language to clarify when a laboratory is required to pay a certificate fee and when the certificate is issued. We removed the listing of the individual certificates in the first paragraph of this section as all certificates go through the same process. The current regulation text specifies when a certificate fee is required, but we wish to clarify with more specific wording. The certificate fee is currently incurred when the original certificate is issued; when the certificate is subsequently renewed; if there is a change in certificate type requiring a new certificate to be issued; or if a lapsed certificate is reactivated with a gap in service and therefore reissued. The intent of the regulation is not changing. We believe adding this clarification would improve transparency concerning the requirement to pay certificate fees.

Specifically, at § 493.638(a)(1) for registration certificates, we proposed to remove the reference to the CoC because we believe the flat fee charged for a CoR and the temporary nature of the certificate require a separate section. We proposed to redesignate the fees associated with a CoC to a new provision at § 493.638(a)(5) to keep fee information relevant to the different certificate types separate, rather than referencing the certificate types together.

At § 493.638(a)(2) for CoW, we proposed to add the costs incurred by FDA to determine whether a test system meets the criteria for waived status, as specified at § 493.15(d). A CMS representative reviews an application for a CoW to determine whether the applicant has requested a CLIA certificate that covers the testing they have listed on the application that they will be performing. The cost of such a review is already part of the CoW fee. However, FDA must expend resources reviewing tests, procedures, and examinations to determine whether a test meets the criteria to be designated as waived. This expense is not currently captured in the fee for a CoW, and we proposed that it should be. HHS had delegated the responsibility to FDA for the review of test systems and assignment of complexity, including what is required by § 493.15(d). CMS compensates FDA out of the CLIA funds for this determination under the CMS–FDA MOU (IA19-23). CoW laboratories are restricted to using waived tests. We believe that the regulatory restrictions of test systems for the CoW laboratories and the CMS requirement to determine what tests can be performed in a CoW laboratory under § 493.15(d) require us to place this fee on the CoW laboratories alone. We believe the predicted increase in CoW laboratories will offset expected increases in the obligation to FDA for the continued process of review and categorization of tests as waived.

We proposed to make editorial changes to clarify the current provision § 493.638(b) that describes certificate fee amounts. We proposed to separate this section into four shorter paragraphs designated as § 493.638(b)(1) through (4). Proposed § 493.638(b)(1) stated that CMS will publish a notice in the **Federal Register** when assessed fees are adjusted in accordance with § 493.680. This section also includes a brief discussion of the basis for certificate fees as set

forth in § 493.638(c). Proposed § 493.638(b)(2) stated that certificate fees would be collected at least biennially. Certificate fees may be assessed more frequently than every 2 years if the laboratory changes its certificate type. Proposed § 493.638(b)(3) stated how fees would be determined and proposed § 493.638(b)(4) stated that CMS would notify the laboratories when the fees are due and the fee amount. This currently takes place in the form of a fee coupon sent through U.S. Mail by the Billing and Certificate Issuance contractor.

We also proposed to move the regulatory text currently found at § 493.643(c)(1) through (3) to a new provision at § 493.638(c) to align the provisions more closely for laboratory schedules and specialties with the related provisions concerning certificate fees. Our intent is to refer back to this provision when the compliance fees are discussed. In addition to redesignating this regulatory text, we proposed making minor changes to clarify the regulatory text related to specialties of service before those specialties are explained at § 493.643(c)(3).

At the proposed new § 493.638(c)(3), we proposed to redesignate the regulatory text currently at § 493.643(c)(1) with changes. We believe that the separation of Schedule A into two parts at § 493.643(c)(1)(i)(A) and (B) was confusing, and we proposed listing them as separate schedules. The proposed text in the new provision § 493.638(c)(3) included § 493.638(c)(3)(i) through (xi). At § 493.638(c)(3)(i), we proposed describing the low volume schedule as Schedule V to differentiate it from Schedule A, proposed at § 493.638(c)(3)(ii). Current data processing system requirements have been built to refer to the low volume A schedule laboratories as Schedule V and will continue with the new data system.

We received public comments on these proposals. The following is a summary of the public comments we received and our responses.

Comment: Several commenters supported the proposed increase in fees, including the fees for replacement certificates. However, several other commenters expressed concerns about the fee increase and new fees, specifically, the potential impact on rural areas or smaller laboratories, including private physician office laboratories. Commenters stated laboratories in

this defined population may need to limit, reduce or discontinue services, which would negatively impact the populations served. Commenters stated many laboratories already experience hardship with growing labor costs, combined with shortages and increased costs of supplies and that raising CLIA fees presents another hardship. Several commenters expressed concerns about raising the CLIA laboratory fees during a time when CMS has made cuts to laboratory test reimbursement under the Protecting Access to Medicare Act (PAMA). The commenters stated that broad increases in regulatory costs may adversely impact the ability to provide clinical laboratory services, particularly in resource-limited settings.

Response: As a user-fee funded program, CLIA must collect fees to cover the cost of implementing the program. However, the existing fee collections are not sufficient to cover total costs of laboratory oversight. The CLIA fees are structured on annual test volume and number of specialties so that smaller (lower annual test volume) laboratories' fees are less than larger (higher annual test volume) laboratories. The fee increase allows us to fund and sustain the CLIA program to ensure oversight of laboratory testing. We note that reimbursement rates are outside the scope of the rule, are set by statute, and are not related to raising the CLIA fees.

Comment: Several commenters requested CMS provide transparency in how the 20 percent increase in 2019 stabilized the CLIA program and publish additional detail related to the CLIA total program costs.

Response: We thank the commenters for these comments. The funds collected in the CLIA program must maintain funding levels to sustain the program. The 2019 20 percent across the board increase was used to shore up the program facing crucial deficiencies at that time. The increase implemented in this final rule is meant to stabilize the program so that adjustments based on inflation will apply automatically. While we proposed a 20 percent across the board increase, based upon our analysis in section I. of this final rule and Table 3, we are instead finalizing an 18 percent across the board increase based on consideration of updated inflation assumptions, laboratory counts, workload estimates and available funds. CMS reviewed updated

estimates of program spending, user fee collections, carryover, and inflation. As displayed in Table 3, we found that increases in actual carryover, actual collections, new and increased fee collections and estimated changes in CPI-U, when applied to actual program obligations, allowed CMS to assess a lower across-the-board inflation factor to the existing user fees and still meet planned carryover targets.

Comment: A commenter stated that the activities associated with processing CLIA certificates of waiver at the State Agency should be allocated more effectively.

Response: We appreciate the commenter's input, but this is outside the scope of the rule. The fees from all collections are used to support the whole of the CLIA program including activities for waived laboratories and the FDA's role in categorizing tests and test systems as waived.

Comment: Several commenters expressed concerns that the fee increase will negatively impact the small office laboratories and private physician laboratories as these types of laboratories will not be profitable enough to offer services or will severely limit services. Commenters further expressed concerns that most of these laboratories are still being negatively impacted by the public health emergency and requested that CMS consider suspending the fee increase for these laboratory types for at least 2 years.

Response: The CLIA regulations were framed to establish quality standards for all laboratories regardless of size or facility type. As such, collection of fees from all types of laboratories is necessary in order for the program to be self-funded as mandated by statute. As previously noted, the CLIA fee schedule is structured so that the lowest volume laboratories pay the lowest CLIA fees. We appreciate the commenters sharing these concerns, but believe it is necessary to finalize the proposed fee increase at this time in order to sustain the CLIA program.

After consideration of the comments received, we are finalizing the proposed changes to § 493.638 without modification. As discussed previously, after recalculating the needs of the

program using updated data, we are finalizing an across the board increase of 18 percent that will be applied to all fees, except for replacement and revised certificates.

C. Changes to Fees for Revised and Replacement Certificates (§ 493.639)

At § 493.639, we proposed to revise the current section heading ("Fee for revised certificate") to read as "Fee for revised and replacement certificates" to match the contents of the section as amended to include both revised certificates and replacement certificates. We proposed to define and explain revised and replacement certificates in section II.A. of the proposed rule. In the proposed provision at § 493.639, we explained the fees associated with each type.

At § 493.639(a), we proposed removing the reference to registration certificates as the section applies to all CLIA certificate types under the statutes. We also proposed to amend the circumstances in which a laboratory may request a revised certificate to include changes to laboratory name and location, LD, or services offered (specialties and subspecialties). We proposed the fee be based on the national average cost to issue the revised certificate. However, due to differing amounts of work required per certificate type, the fee is not the same for all certificate types. Please see Table 6.

We determined the time and resources required to enter changes to laboratory demographics, review of specialties and subspecialties, and review of LD qualifications using an average of the State survey agencies' calculated unit hourly cost. The State unit hourly cost is determined by the CLIA budget office and is based on a formula of total State costs divided by the total paid hours. The total State costs are reported to CMS by the State survey agencies and include staff salaries as determined by each State's civil service pay scale, fringe benefits, travel costs, and other costs such as office supplies, computers containing software required to perform and report a CLIA survey, etc. The total staff year hours are determined by multiplying the number of full-time employees (FTE) by 1600 hours, representing the productive work year.

The time and resources for State agencies to enter demographic changes are less than those where the qualifications of the LD or services need to be reviewed to ensure CLIA personnel requirements are met. Review of LD qualifications applies to laboratories holding a CoC, a certificate for PPM, or CoR.

AOs are responsible for reviewing CoA LD qualifications, and the AO is also responsible for reviewing the addition of specialties and subspecialties for the CoA laboratory. As such, State agency staff are not responsible for reviewing LD qualifications or changes in specialties/subspecialties for laboratories with a CoA; however, they are responsible for processing the other demographic change requests for CoA laboratories. Therefore, a revised certificate for a CoA laboratory does not include the cost to review the qualifications of LDs, nor does it include the adding or deleting of specialties or subspecialties.

For a CoC, a change in services (adding or deleting a specialty or subspecialty) does not include review to determine compliance with the regulations for services added; however, the entry or deletion of specialty or subspecialty changes requires State agency personnel time and resources.

CLIA personnel requirements are not required for laboratories with a CoW, nor are there specialty or subspecialty requirements. Therefore, the time and resources required to enter requested demographic changes for CoW laboratories are less than for other certificate types. Please see the section below for the calculations used to determine these fee amounts.

We proposed the following fees for issuing revised certificates:

TABLE 6: CMS Proposed Fee for Issuance of Revised Certificate

Certificate Type	Fee
CoW	$95.00
CoA	$95.00
CoR	$150.00
CoC	$150.00
PPM	$150.00

The revised certificate fee would be paid prior to the issuance of the revised certificate.

At § 493.639(a)(1), we proposed a new provision explaining that the addition of services (that is, specialties/subspecialties) for laboratories with a CoC may result in an additional fee for purposes of determination of compliance if added services require an inspection. That addition of the specialties inspection fee is described in a new provision at § 493.643(d)(2).

We proposed to delete the current provisions at § 493.639(b)(1) and (2), which provide information on fees for issuing a revised certificate and scenarios that describe changes that may require a change in certificate. We proposed to replace them with a new provision at § 493.639(b) that outlines fees for issuing a replacement certificate. We believe the current provisions are confusing as written as is the location of the provisions in the regulations.

At the new provision § 493.639(b), we proposed a fee for issuance of replacement certificates as discussed in section II.A. of the proposed rule. The proposed requirement must account for the time and resources required to issue a replacement certificate when requested. Historically, replacement certificates have been issued without additional fees when a laboratory loses or destroys its current certificate. As discussed in the proposed rule, we have determined that the actual cost of issuing a replacement certificate is $75.00. A replacement certificate is one where no changes are being requested. The fee would be paid prior to the issuance of the replacement certificate.

The initial calculations used to determine the proposed fee amounts for replacement certificates, and revised certificates were based on the time, and the average State unit costs for 2019 when these fees were set. When these calculations were made, the national average unit hourly cost in 2019 was $72.06. It was determined that it took State agency personnel approximately 45 minutes to receive, review, and enter a request for a replacement certificate and another 15 minutes to print and mail the certificate. Using these estimates, the cost of the replacement certificate is calculated to cost the CLIA program $75.00 currently.

Furthermore, CMS determined that additional State agency resources are expended when issuing revised certificates as follows:

- An additional 15-20 minutes to review and enter requested demographic changes or $20.00 for all certificate types.

- An additional 45 minutes to review and enter requested laboratory director changes or specialty changes for $55.00 for revised CoRs, CoCs, and PPMs.

These additional costs are therefore reflected in the proposed fees for issuing revised certificates. (See Table 6)

We received public comments on these proposals. The following is a summary of the public comments we received and our response.

Comment: Several commenters suggested CMS establish a process that would allow a laboratory to print its own certificates, rather than having to request and pay a replacement certificate fee as proposed. The commenters asserted that the established process of mailing and relying on mail delivery service is outdated and antiquated and that often the laboratory may not receive a copy of the certificate, due to mail delivery interruptions.

Response: We thank the commenters for this suggestion. As of March 2023, CMS began issuing a link to electronic certificates so laboratories could print their own certificate.

After consideration of the comments received, we are finalizing the proposed changes to § 493.639 without modification.

D. Changes to Fees Applicable to Laboratories Issued a CoC (§ 493.643)

At § 493.643, we proposed renaming the section heading "Fee for determination of program compliance" to "Additional fees applicable to laboratories issued a certificate of compliance" for clarification.

We proposed adding language at § 493.643(b) to describe the costs included in the fee for routine inspections to increase transparency. We proposed deleting the second sentence of § 493.643(b) in consideration of a two-part biennial fee increase as discussed under section II.H. (§ 493.680) of the proposed rule and this final rule. For clarity, we proposed to redesignate the third sentence of the current provision at § 493.643(b) as § 493.643(c).

At the new provision § 493.643(c)(1), we proposed that the inspection fee will be based on the schedules of the laboratories as defined in the new provision under § 493.638(c)(3). The fee amounts assigned to the schedules in the February 1992 final rule were based on an estimated number of hours to perform a survey of a laboratory with the scope and volume associated with each schedule multiplied by an estimated 1992 hourly rate for a surveyor of $35.00. The established hourly rate of $35.00 was intended to be used as a baseline and then revised after actual data were collected and experience gained (57 FR 7193). In 1992 it was anticipated that the universe of regulated laboratories would be much greater than those regulated prior to the implementation of CLIA '88.

The hourly rate for performing laboratory surveys is recalculated by CMS for each State annually to determine the CLIA obligation to support the State survey agencies but has not been used to increase CLIA fees on an ongoing basis. The national average hourly rate in 2023 is $108.78, to reflect updated data. A description of the national average hourly rate calculation is provided in section II.C. of the proposed rule.

Extensive data collected over time now enables us to better estimate the number of hours it takes for a surveyor to perform an inspection of a laboratory within each schedule. Such estimates are primarily driven by the scope and volume of tests run by the laboratory and the laboratory's compliance with the CLIA regulations. A laboratory with a high-test volume and multiple specialties may have processes and practices that allow it to meet and exceed CLIA regulations as they operate with a high degree of quality and efficiency while ensuring reported results are accurate and timely to provide optimum patient care. The surveyor will likely spend less time on inspecting that laboratory. In contrast, if a laboratory with a small test volume and few specialties does not have processes and practices that allow it to operate with the same high degree of quality and efficiency, such a laboratory is likely not to meet the CLIA requirements. Such laboratories may be reporting test results that may not be accurate and reliable. While the

test volume may be low, the surveyor will likely spend additional time surveying such laboratories due to the less-than-optimal operations and processes.

Conversely, the number of hours needed to survey a large laboratory with poor compliance history could be quite large. The surveyor would spend more time in this laboratory, and given the size and poor compliance history, the surveyor would review the prior survey deficiencies to ensure the laboratory's monitors put into place have corrected the deficiency. In contrast, a surveyor may not need to spend as many hours to survey a laboratory with lower test volume and specialties and a favorable compliance history. Taking each scenario into account, we believe the average number of hours a surveyor spends in each laboratory reflects the universe of laboratories within each schedule. Thus, as we explained in the proposed rule, we will not be changing the differences between the amounts of the fees within the compliance fee schedules relative to each other. They will remain in their relative amounts and be increased across the board by the same percentage in the proposed two-part fee increase (section II.H. (§ 493.680) of the proposed rule and this final rule).

Table 7 illustrates the different scenarios mentioned previously in the proposed rule and this final rule and how the number of hours spent on the survey vary based on both the size (the schedule) of the laboratory and poor compliance with the CLIA regulations. Poor compliance is being defined for this illustration as a laboratory with at least one condition-level deficiency cited during a survey. For information about condition-level deficiencies, please see the CLIA website for the Interpretive Guidelines for Laboratories, Appendix C: Interpretive Guidelines.[14]

[14] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf.*

TABLE 7: Survey Hours with Condition-Level Deficiencies Cited vs. Not Cited by Schedule Code

	Condition Level Deficiencies Not Cited		Condition Level Deficiencies Cited	
Schedule code of laboratories that were surveyed*	**Number of laboratories****	**Range of hours required to perform the individual surveys and the average (avg) number hours****	**Number of laboratories****	**Range of hours required to perform the individual surveys and the average (avg) number of hours****
V-A	3,446	4 – 69 (avg: 12)	661	5 – 143 (avg: 18)
B-C	1,328	4 – 69 (avg: 13)	320	7 – 123 (avg: 19)
D-E	972	4 – 79 (avg: 15)	261	6 – 201 (avg: 23)
F-G	727	5 - 165 (avg: 18)	192	6 – 378 (avg: 30)
H-I	935	5 – 284 (avg: 21)	279	7 – 497 (avg: 41)
J	110	8 – 213 (avg: 32)	23	8 – 378 (avg: 75)

*For a description of the schedules see the section of this document with the proposed amendments to 42 CFR chapter IV, specifically provision § 493.638(c). The schedules have been grouped as two schedules together to keep the size of the table to a minimum. We did not propose to change the schedules this way.

**The data comes from the SAS Viya system for surveys completed between 10-01-2017 and 09-30-2019 with condition-level deficiencies not cited versus condition level deficiencies cited and separated by schedule codes.

As illustrated in Table 7, survey hours in small laboratories without condition level deficiencies averaged 12 hours. In contrast, survey hours in small (schedules V-A) laboratories with condition level deficiencies averaged 18 hours. In the largest (schedule J) laboratories, survey hours differed from an average of 32 hours spent in laboratories without condition level deficiencies compared to 75 hours in those laboratories that had condition level deficiencies cited.

The February 1992 final rule did not consider other costs involved in the inspection process, such as continuous training of the State surveyors and monitoring of the State agency program processes by the CMS Locations (Regional Offices). The CLIA program has created and continuously updates periodic training for surveyors through online training modules, onsite meetings, and conference calls.

The surveyors are individually monitored with a Federal Monitoring Survey (FMS) process where CMS location (Regional Office) Federal surveyors observe the individual State surveyor on a survey or perform a survey of the same laboratory after the State surveyor has completed their survey to confirm that the State surveyor is competent and following the prescribed survey process. The CMS locations (Regional Offices) also perform an annual State Agency Performance Review (SAPR) for each State survey agency, including a review of the State survey agency's training processes and monitoring processes for their State surveyors. This

includes a review of the deficiency reports State surveyors have sent to laboratories to determine that the surveyor is following the program's principles of documentation and the proper survey process.

There are also costs to the program to maintain a computerized system for entering inspection findings and compliance monitoring, including proficiency testing. The computer system also allows the CMS locations to run reports to monitor the inspections entered by the State surveyors.

The compliance fees have historically been based on the costs to the CLIA program for the State agencies. These aforementioned activities are obligations outside of the State survey agency annual budgets. We therefore proposed that inspection fees for laboratories in each schedule and State will no longer be determined solely by the estimated hours spent on a survey of a laboratory within each schedule nor by the surveyor hourly rate of $35.00 established in 1992.

We believe that the compliance fees currently set within the schedules should continue to be used but that additional fees, as previously described, should be added to the regulatory scheme. All fees would be increased biennially following the biennial two-part fee increase as proposed in the proposed rule in § 493.680.

We believe we are authorized to calculate these fees per laboratory schedule (or group) even though the fees will no longer be determined solely by the estimated hours spent on a survey of a laboratory within each schedule nor by the 1992 surveyor hourly rate of $35.00 based on section 353(m)(3)(C) of the PHSA, which states that, fees shall vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories. As discussed in the proposed rule, we believe our proposals are within the bounds of our authority under the PHSA.

At § 493.643(c)(2), we proposed to redesignate language from the current § 493.643(b) which states the fees are assessed and payable biennially. We stated that we believe this will support the two-part fee increase proposed in the proposed rule and described in § 493.680.

At the new provision § 493.643(c)(3), we proposed that the fee amount would be the amount applicable to a given laboratory increase listed in the most recent published CLIA fee increase notice in the **Federal Register.**

We proposed to redesignate current § 493.643(d)(1) and (2) where additional fees for CoC laboratories are discussed as § 493.643(d)(2) and (3) and to redesignate the fourth and fifth sentences of current provision § 493.643(b) where an additional fee for a follow-up survey on a CoC laboratory is discussed as a new provision at § 493.643(d)(1). We believe the discussion of additional fees for CoC laboratories should be grouped together.

We proposed to move the current regulatory text at § 493.643(d)(2) to § 493.643(d)(3) with no changes. Current regulation allows additional fees to be assessed for substantiated complaints; however, this has not been implemented. The proposed rule would implement fees for substantiated complaints, meaning those complaints where the allegations against the laboratory were found to be true by CMS. We believe implementing the fee for substantiated complaints would cover the costs required to perform such a survey, including documenting the deficiencies found to be violated, preparing a report for the laboratory, and review of the laboratory's plan of correction and monitoring their correction. The fee was proposed to be limited to the cost of the actual time and resources required for these activities.

At new provision § 493.643(d)(4), we proposed to establish an additional fee for CoC laboratories that are found to have unsuccessful PT through a PT desk review. Current policy requires the review of PT performance every 30-45 days for each laboratory with a CoC that performs testing and is enrolled in PT for an analyte or test included in subpart I. Cases of unsuccessful PT performance require a PT desk review to confirm. Upon confirmation, the laboratory is notified of its regulatory requirement to investigate and correct the unsuccessful PT

performance. Currently, such PT desk reviews do not generate an additional fee; however, conducting the desk review requires surveyor time and resources. We believe this new fee would cover the costs of the desk review, including documenting the deficiencies found to be violated, preparing a report for the laboratory, and reviewing the laboratory's plan of correction and monitoring their correction. The proposed fee is to be limited to the cost of the actual time and resources required for these activities. We stated in the proposed rule that only laboratories with unsuccessful PT performance would be impacted if this rule is finalized.

The fees described in § 493.643(d) must be paid, or HHS will revoke the laboratory's CoC.

We did not receive public comments on the proposed changes to § 493.643 and are finalizing as proposed.

E. Changes to Additional Fees Applicable to Laboratories Issued a CoA, CoW, or Certificate for PPM Procedures (§ 493.645)

At § 493.645, we proposed to change the current section heading ("Additional fee(s) applicable to approved State laboratory programs and laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures") to clarify the contents of the section as amended. The proposed title was "Additional fees applicable to laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures."

We proposed to move in its entirety the regulatory text regarding the fee we charge State laboratory programs for costs related to their CLIA-exempt laboratories in § 493.645(a)(1) through (3) to § 493.649(a)(1) through (3). We believe the fees for approved State laboratory programs should be listed separately from the other CLIA-certified laboratories in the regulations. A State laboratory program is a laboratory program that HHS approves as exempt due to the State requirements being equal to or more stringent than the CLIA requirements. Under such programs, the State provides regulatory oversight of its laboratories in lieu of such laboratories being regulated by HHS. HHS approves and monitors such State laboratory

programs to ensure that the standards of the State laboratory programs are and remain at least as stringent as the CLIA regulations. HHS does not impose fees on laboratories covered by these programs but charges a fee to the program as described in the new provision at § 493.649.

We proposed making editorial corrections to the references of §§ 493.645(a) and 493.646 noted in §§ 493.557(b)(4) and 493.575(i) and replacing those references with §§ 493.649(a) and 493.655(b). The requirements previously included at §§ 493.645(a) and 493.646(b) governing applicable fees were proposed to be redesignated as § 493.649(a) and new § 493.655(b).

We further proposed redesignating current § 493.645(b)(1) and (2) regarding the payment of inspection fees as new § 493.645(a)(1) and (2). We proposed new § 493.645(a)(1) to clarify the amount accredited laboratories pay for their inspection (validation survey) fees by removing the last sentence of the current regulatory text, which reads that these costs are the same as those that are incurred when inspecting nonaccredited laboratories. We believe this does not fully explain how the fee is determined. This fee is based on fees that CoC laboratories pay for compliance inspections; however, an accredited laboratory is only assessed 5 percent of the fee a CoC laboratory pays because only 5 percent of CoA laboratories are inspected (undergo a validation survey) annually. For example, a CoC laboratory classified as "schedule D" currently pays an average biennial compliance fee of $2,336.00. The accredited laboratory classified as "schedule D" would currently pay an average biennial inspection (validation survey) fee of $117.00.

At new § 493.645(a)(2), we proposed redesignating the provision from current § 493.645(b)(2), with no changes. This provision established an additional fee if a laboratory issued a CoA were to be inspected and follow-up visits were necessary because of identified deficiencies. Historically this fee had not been implemented due to technical difficulties described previously in the proposed rule. We proposed that it be implemented. As stated in the current regulatory text, the additional fee to cover the cost of these follow-up visits would be

based on the actual resources and time necessary to perform the follow-up visits. Also, as stated in the regulatory text, HHS would revoke the laboratory's CoA for failure to pay the fee.

At new § 493.645(b), we proposed redesignating the provision from current § 493.645(c). This provision established a fee for substantiated complaint surveys, those in which the allegations against the laboratory were found to be true, on CoA, CoW, or certificate for PPM procedures laboratories. Historically, this fee has not been implemented. We believe implementing the fee for substantiated complaints would cover the costs required to perform such a survey, including documenting the deficiencies found to be violated, preparing a report for the laboratory, and review of the laboratory's plan of correction and monitoring their correction. The fee is limited to the actual time and resources required for these activities.

We did not receive public comments on the proposed changes to §§ 493.557, 493.575, and 493.645 and are finalizing as proposed.

F. Changes to Additional Fees Applicable to Approved State Laboratory Programs (§ 493.649)

At § 493.649, we proposed to delete the current language in its entirety and replace it with language from § 493.645(a)(1) through (3). We stated in the proposed rule that the current provision at § 493.649 would no longer be needed as the methodology for determining inspection fees because the proposed rule was not based on a surveyor hourly rate. At new § 493.649, we proposed revising the current section heading ("Methodology for determining fee amount") to give a clear meaning of the contents of the section as amended. The proposed title was "Additional fees applicable to approved State laboratory programs." We proposed replacing the current language with current provisions § 493.645(a)(1) through (3) with minor changes (removing "costs of" from current 493.469(a)(3)). The provisions at § 493.645(a)(1) through (3) outline the fees applicable to approved State laboratory programs and have been comingled with the provision that outlines the fees for accredited PPM and CoW laboratories. We believe separating this provision from the other laboratory certificate types will allow for improved readability and understanding.

We did not receive public comments on the proposed changes at § 493.649 and are finalizing as proposed.

G. Changes to Payment of Fees (§§ 493.646 and 493.655)

At § 493.646, we proposed redesignating the current provision with minor changes corresponding to the validation survey cost as new § 493.655 and including a reference to § 493.563 that contains the validation inspection information. We believe this provision which outlines the payment of fees, is better placed after discussions of the different types of fees.

We proposed redesignating § 493.646(a) and (b) where the payment of fees is discussed to new provisions at § 493.655(a) and (b) with a minor change referencing approved State laboratory programs instead of State-exempt laboratories. The State program pays CMS, not the individual laboratories.

We did not receive public comments on the proposed changes at §§ 493.646 and 493.655 and are finalizing as proposed.

H. Methodology for Determining the Biennial Fee Increase (§ 493.680)

At new provision § 493.680, we proposed a biennial two-part fee increase, which would be calculated as described in section I.B. of the proposed rule and published as a notice with a comment period at least biennially. Should the off-year of the biennial increase result in unexpected program obligations, CMS may need to calculate an additional fee increase based on either the CPI-U or difference in obligations and total collected fees or a combination of both. Any unexpected program obligations that are identified during the off-year would be incorporated into the biennial increase. All fees, existing and proposed, mentioned in the proposed rule would also be subject to the biennial two-part fee increase.

We did not receive public comments on proposed § 493.680 and are finalizing as proposed.

III. Provisions for CLIA Requirements for Histocompatibility, Personnel, and Alternative Sanctions for CoW Laboratories

This final rule amends subpart K – Quality System for Nonwaived Testing, subpart M – Personnel for Nonwaived Testing, and subpart R – Enforcement Procedures in the CLIA regulations. This section provides an overview of the proposed revisions to the CLIA requirements for histocompatibility, personnel, and application of alternative sanctions for CoW laboratories originally established by the February 1992 final rule with comment period (57 FR 7002), subsequently modified in 1995[15] and 2003,[16] and currently specified in subpart A − General Provisions, subpart K − Quality System for Nonwaived Testing, subpart M – Personnel for Nonwaived Testing, and subpart R – Enforcement Procedures. We also summarize and respond to comments on the July 2022 proposed rule in this section and summarize the final actions for each of the new or revised sections of the regulations.

We received 20,574 public comments in response to the July 2022 proposed rule. The commenters represented individuals, laboratory accreditation organizations, laboratory professional organizations, government agencies, healthcare organizations, and businesses, including in vitro diagnostics manufacturers. The majority of the comments were a standard "form letter" opposing the proposal to include nursing degrees in the qualifications for high complexity testing personnel. In addition to the duplicate form letters, we received over 750 comments related to the inclusion of nursing degrees for moderate and high testing personnel qualifications.

A. Changes to Histocompatibility Requirements

In the proposed rule, we proposed to amend the histocompatibility regulations under CLIA by removing obsolete regulations and removing requirements that are also imposed under the general requirements. We also proposed to update the histocompatibility regulations to incorporate current practices and technological changes in Human leukocyte antigen (HLA) typing, antibody screening and identification, crossmatching and transplantation.

---

[15] 60 FR 20047, April 24, 1995 (*https://www.govinfo.gov/content/pkg/FR-1995-04-24/pdf/95-9953.pdf#page=13)*.
[16] 68 FR 3640, January 24, 2003 (*https://www.govinfo.gov/content/pkg/FR-2003-01-24/pdf/03-1230.pdf*).

1. General, Human leukocyte antigen (HLA) Typing, Disease-Associated Studies, and Antibody Screening and Identification (§ 493.1278(a) through (d))

At § 493.1278(a)(1), we proposed to amend the requirement by changing "an audible alarms system" to "a continuous monitoring and alert system" because this allows the laboratories more flexibility in determining the best way to monitor refrigerator temperatures. It is very important to monitor temperatures continuously, so that recipient and donor specimens and reagents are stored at the appropriate temperature to ensure accurate and reliable testing.

At § 493.1278(a)(2), we proposed to modify the requirement by expanding the regulatory language to include that the laboratory must establish and follow written policies and procedures for the storage and retention of patient specimens based on the specific type of specimen because the type and duration of specimen storage are equally important as ease of retrieval. We are retaining the requirement that stored specimens must be easily retrievable.

At § 493.1278(a)(3), we proposed deleting the labeling requirement for in-house prepared typing sera reagent. If a laboratory is performing histocompatibility testing, this requirement under the general reagent labeling requirements for all test systems must be met under § 493.1252(c) and, therefore, is duplicative.

At § 493.1278(a)(4), we proposed to revise this requirement by removing the examples (that is, antibodies, antibody-coated particles, or complement) to clarify that these technologies, as well as current and future technologies, are allowed for the isolation of lymphocytes or lymphocyte subsets. We also proposed clarifying the requirement by adding "identification" of lymphocytes, or lymphocyte subsets. In this type of testing, lymphocytes can be isolated, but the subsets (B and T cells) are identified rather than isolated. Due to the proposed changes to § 493.1278(a)(3), we also proposed to redesignate § 493.1278(a)(4) as revised to § 493.1278(a)(3).

We proposed the current requirement at § 493.1278(a)(5) would be redesignated as § 493.1278(a)(4). This requirement remains unchanged.

At § 493.1278(b)(1) through (3), we proposed deleting these requirements pertaining to establishing HLA typing procedures. The requirement that the laboratory must establish and have written procedures that ensure quality test results are already addressed by the general requirements for all test systems under current § 493.1445(e)(1) and (e)(3)(i) and revision at § 493.1278(f), respectively, and therefore, are duplicative.

The July 2022 proposed rule inadvertently omitted a technical change at proposed redesignated § 493.1278(b)(1) to reflect the current name of the World Health Organization (WHO) committee that determines HLA nomenclature, the "Nomenclature Committee for Factors of the HLA System." The finalized regulation text at newly redesignated § 493.1278(b)(1) incorporates this change and is shown in its entirety in the final regulatory text.

At § 493.1278(b), we proposed to redesignate the provisions at paragraph (b)(4) to paragraph (b)(1). At newly redesignated paragraph (b)(1), we proposed deleting the language that states potential new antigens not yet approved by this committee must have a designation that cannot be confused with WHO terminology because new alleles are approved monthly, which makes this requirement obsolete.

At § 493.1278(b)(5)(i) through (iv), we proposed deleting the requirements for preparation of cells or cellular extracts, selecting typing reagents, ensuring that reagents used for typing are adequate, and assignment of HLA antigens as they are already addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, and 493.1252, and therefore, are duplicative.

At § 493.1278(b)(5)(v), we proposed to modify the requirement to add "allele" and delete the "re" prefix in the word "retyping" in this paragraph and to redesignate the provisions at paragraph (b)(5)(v) to paragraph (b)(2). We proposed inserting "allele" because the regulation only has antigen typing, but there is typing done at the allele level. We proposed deleting the "re" prefix to remove redundancy under the proposed revision at § 493.1278(b)(2) which requires the laboratory to have written criteria to define the frequency for performing typing.

At § 493.1278(b)(6)(i) through (iii), we proposed deleting requirements for HLA typing control materials procedures as they are addressed by the general requirements regarding quality control materials and procedures for all test systems under § 493.1256(a) through (d) and (f) through (h), and therefore, are duplicative.

At § 493.1278(c), we proposed deleting this requirement for control procedures and materials regarding disease related studies because this is addressed by the general requirements for all test systems under §§ 493.1256(d) and 493.1451(b)(4), and therefore, is duplicative.

At § 493.1278(d), we proposed changing the name of this section from "Antibody Screening" to "Antibody Screening and Identification" for clarification as both processes apply to histocompatibility testing. The provisions covered under this section apply to both screening and identification. We proposed moving § 493.1278(d) as revised to § 493.1278(c).

At § 493.1278(d)(1) through (3) and (5) through (7), we proposed deleting these requirements for antibody screening laboratory procedures as they are addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1252, and 493.1256, and therefore, are duplicative.

We received public comments on these proposals at § 493.1278(a) through (d). The following is a summary of the public comments we received and our responses.

Comment: A commenter supported the modification under § 493.1278(a)(1) requiring the use of a continuous monitoring system and alert system to monitor the storage temperature of specimens but added that this may result in an additional burden for smaller laboratories with limited funds.

Response: Many continuous monitoring systems have alerts built into the system. Laboratories can also develop policies and procedures for an alert system built upon the results of the continuous monitoring system. We believe that the risk associated with the incorrect storage temperature of specimens and reagents warrants the requirement for an alert system.

Comment: A commenter proposed new language for existing standards at § 493.1278(d)(1) to "use a technique that detects HLA-specific antibody that is equivalent or superior to the solid phase assays" and § 493.1278(d)(3) to "use a panel composition that contains all major HLA specificities" to remain in alignment with the United Network for Organ Sharing (UNOS) requirements.

Response: In the proposed rule, we proposed to delete § 493.1278(d)(1) and (d)(3) as we believe they are addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1252, and 493.1256. LDs can choose to implement UNOS requirements as part of their responsibilities indicated under § 493.1445(e)(3)(i). Therefore, we are not making any language change and are finalizing the proposed deletion of § 493.1278(d)(1) and (d)(3).

Comment: A commenter suggested the inclusion of current § 493.1278(d)(5) "have available and follow a written policy consistent with clinical transplant protocols for the frequency of screening potential transplant beneficiary sera for preformed HLA-specific antibodies."

Response: We believe the general requirements for all test systems under § 493.1251 address the requirement for laboratories to have available and follow written policies. Therefore, we are finalizing the proposed deletion of § 493.1278(d)(5).

Comment: Several commenters suggested the removal of the word "serologic" in the proposed language for crossmatching at § 493.1278(d)(2)(iv) to account for allele-specific antibody detection. Another commenter stated that serologic typing is insufficient for current clinical histocompatibility testing due to its many limitations, including low specificity at certain loci and the potential for certain false negative results, and suggested changing the language to "typing of the donor by molecular methods at the serologic split antigen equivalent."

Response: We agree with the commenters that removing "serologic" will maintain flexibility with the evolution of testing practices. We are not specifying molecular methods, but

instead, are modifying our proposed revisions to remove reference to the "serologic" level at revised § 493.1278(d)(2)(iv).

We received no comments on proposed § 493.1278(a)(2) through (4) and (c) and are finalizing these provisions as proposed.

After consideration of the comments received, we are finalizing the proposed changes at § 493.1278(a) through (d), with the following modifications to the proposed revisions at (b)(1) and (d)(2)(iv):

- To update the regulation at redesignated § 493.1278(b)(1) to incorporate the revised name of the World Health Organization (WHO) committee that determines HLA nomenclature, "Nomenclature Committee for Factors of the HLA System."
- To finalize the proposed revisions at § 493.1278(d)(2)(iv) with modification, to remove "at the serologic level".

2. Crossmatching and Transplantation (§ 493.1278(e) and (f))

At § 493.1278(e)(1) through (3), we proposed removing these three requirements regarding the laboratory having crossmatch procedures and controls as we believe the provisions to be removed are addressed by the general requirements for all test systems under §§ 493.1445(e)(1), 493.1251, 493.1256, and 493.1451(b)(4), and therefore, are duplicative.

Since 1992, there have been important advances in the field of transplantation and histocompatibility. Based on comments received in response to the 2018 RFI and interested parties and CLIAC input, we understand the current regulations at § 493.1278 do not reflect the standard practice for laboratories performing testing in the specialty of histocompatibility and are viewed by the transplantation community as a barrier to modernized decision making approaches for organ acceptability. Additionally, we understand that the use of risk assessment and alternative immunologic assessment procedures are currently the standard practice for laboratories performing testing in the specialty of histocompatibility. Therefore, we proposed to

add the requirements summarized below, at § 493.1278(d), to increase flexibility in the regulations and remove perceived barriers. These requirements include:

- Defining donor and recipient HLA antigens, alleles, and antibodies to be tested;
- Defining the criteria necessary to assess a recipient's alloantibody status;
- Assessing recipient antibody presence or absence on an ongoing basis;
- Typing the donor at the serological level, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable;
- Describing the circumstances in which a pre- and post-transplant confirmation testing of donor and recipient specimens is required;
- Making available all applicable donor and recipient test results to transplant team;
- Ensuring immunologic assessments are based on the test report results obtained from a test report from CLIA certified testing laboratory(ies);
- Defining time limits between recipient testing and the performance of crossmatch; and
- Requiring that the test report must specify what type of crossmatch was performed.

At § 493.1278(f), we proposed to change the words "transfusion" and "transfused" to "infusion" and "infused", respectively. The relevance of HLA testing and the decisions of the extent of testing in both a transplant and transfusion setting are critical to both organ and cell acceptance in the host recipient. The use of the word "transfusion" is inappropriate given that the product itself is the transfusion but the action of introducing the product is the process of infusion. Transfusion is more specific to immunohematology. There are specific transfusion regulations in the immunohematology section at § 493.1271 that should not be confused with histocompatibility requirements. Since histocompatibility addresses materials that are not always blood products, we believe the term "infusion" would be more appropriate. We proposed moving § 493.1278(f) as revised to § 493.1278(e).

At § 493.1278(f)(1), we proposed revising this requirement to state that laboratories performing histocompatibility testing must establish and have written policies and procedures

specifying the types of histocompatibility testing. We proposed moving this language to § 493.1278(e). In addition, we proposed adding "identification" after "antibody screening" in the revised § 493.1278(c), as identification is an important part of the process for crossmatching. Finally, we proposed removing "compatibility testing" at § 493.1278(f)(1) because this activity is specific to immunohematology, and crossmatching is a more appropriate description of what we understand is the current histocompatibility procedure used by laboratories. We proposed moving § 493.1278(f)(1) as revised to § 493.1278(e).

At § 493.1278(f)(1), we further proposed modifying the current general requirement to specify that the laboratory must establish and follow written policies and procedures that address the transplant type (organ, tissue, cell) donor type (living, deceased, or paired) and recipient type (high risk vs. non-sensitized). The following terminologies were also updated to reflect current practices: "cadaver donor" is replaced by "deceased donor," "transfused" is replaced by "infused," and "combined" is replaced by "paired." In addition, we believe that clarifying the current regulatory language allows the laboratories to make decisions based on existing technologies and practices for determining what testing is applicable for those transplant programs they serve. We proposed moving § 493.1278(f)(1) as revised to § 493.1278(e)(1).

At § 493.1278(f)(2) through (3), we proposed to remove these requirements for renal and nonrenal transplantation crossmatch procedures which are perceived as obstacles to current practices by the transplant community and instead allow for alternative immunologic assessment procedures to be used in the designated specialty of histocompatibility. The requirements that the laboratory must establish and follow written policies and procedures are already addressed in the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1256(c) through (h), and 493.1451(b)(4) and, therefore, are duplicative. In addition, we proposed adding a new requirement for pre-transplant recipient specimens under the proposed § 493.1278(e)(3). Under this new proposed requirement, the laboratory must have written policies and procedures to obtain a recipient specimen for a crossmatch, or to document its efforts to

obtain a recipient specimen, collected on the day of transplant. We recognize that the laboratory may not be able to obtain a recipient specimen collected on the day of a transplant since this collection process depends upon the physician obtaining the specimen and submitting it to the laboratory.

At § 493.1278(f)(1)(ii), we proposed modifying this requirement for laboratory policies and procedures as it would be included in the amended protocol requirements under the proposed regulation at § 493.1278(e)(1)(i) and (iii), and therefore, would be duplicative. The proposed revised requirement reflects current practices in the histocompatibility community.

At § 493.1278(f)(1)(iii), we proposed replacing "the level of" with "type and frequency" to clarify this revised requirement refers to the type and frequency of testing practice to support the clinical transplant protocols. We also proposed removing the examples of antigen and allele level in the regulation as these examples may not be all-inclusive and generally are reflected in guidance rather than regulatory text. We proposed redesignating § 493.1278(f)(1)(iii) as § 493.1278(e)(2).

The requirement at § 493.1278(g) would be redesignated as § 493.1278(f). This requirement remains unchanged.

We received public comments on these proposals at § 493.1278(e) through (f). The following is a summary of the public comments we received and our responses.

Comment: Several commenters stated that virtual crossmatch is an immunologic assessment, not a test. One of the commenters added that a "test" requires a specific procedure to be performed, and virtual crossmatches are often assessments of existing candidate and donor test results to determine potential immunologic compatibility or the need for additional testing to occur. The commenters suggested modification of the proposed language at § 493.1278(d)(3) and § 493.1278(e) to include immunologic assessment language.

Response: The CLIA regulations refer to "test" and "test systems," and do not refer to "immunologic assessment." We believe this would cause confusion by introducing a new term to

the regulations without defining the term. Therefore, we will incorporate information related to immunologic assessment in updated guidance related to § 493.1278(d)(3) and § 493.1278(e).

Comment: Several commenters requested clarification of the proposed new requirement for pretransplant recipient specimens at § 493.1278(e)(3). Another commenter questioned if the proposed requirement means that (1) laboratories must obtain a specimen on the day of the transplant or document the attempts made to obtain a specimen on the day of the transplant, or (2) laboratories must collect a specimen on the day of the transplant or have documentation of attempts to obtain such a specimen, but documentation could be after the day of the transplant. The second commenter requested additional clarity around the intended use of the proposed recipient specimen for crossmatch to be obtained on the day of the transplant and what the required use of that sample would be, adding that the laboratory and clinical team should be able to define how current a sample must be for candidate testing, as already required in the proposed § 493.1278(d)(2)(viii). The commenter believes the laboratory and clinical team should be able to assess the need for an updated sample after considering timing, potential sensitizing events, and previous candidate alloantibody levels and that it may not be necessary to draw an additional recipient specimen in all cases. The same commenter requested flexibility on pre-transplant samples drawn for young pediatric candidates, stating that the small size of some pediatric candidates can make additional blood volume drawn immediately pre-transplant harmful.

Response: As explained in the proposed rule, we recognize that the laboratory may not be able to obtain a recipient specimen collected on the day of a transplant since this collection process depends upon the physician obtaining the specimen and submitting it to the laboratory. Therefore, we proposed at § 493.1278(e)(3) that the laboratory has a process to obtain a recipient specimen, if possible, for crossmatch collected on the day of the transplant. If the laboratory cannot obtain a recipient specimen on the day of the transplant, it must have a process to document its efforts to obtain the specimen. The laboratory documentation does not have to be on the day of the transplant but could be after the day of the transplant. In this final rule, we are

also adding clarification at § 493.1278(e)(3) that the recipient specimen be collected prior to transplantation on the day of the transplant. Also, as proposed under § 493.1278(e), laboratories must establish and follow written policies and procedures specifying the histocompatibility testing to be performed for each type of cell, tissue, or organ to be infused or transplanted. The laboratory or clinical team must have policies and procedures in place to define when there is a need for additional recipient specimens for immunologic assessment and the circumstances when the collection of additional recipient specimens is not needed, such as in pediatric cases. The laboratory is allowed flexibility to determine its policies and procedures under proposed revised §§ 493.1278(e)(3) and 493.1251.

After consideration of the comments received, we are finalizing the proposed changes at § 493.1278(e) and (f), with modification to the proposed revisions at § 493.1278(e)(3) related to the laboratory process to obtain a recipient specimen, if possible, for crossmatch collected on the day of the transplant and prior to transplantation.

B. Changes to Personnel Requirements

We stated in the proposed rule that CMS recognizes that the COVID-19 public health emergency (PHE) requires flexibility, and that we are committed to taking critical steps to ensure America's clinical laboratories can respond during a PHE to provide reliable testing while ensuring patient health and safety. As such, we requested that the public provide comments regarding how the CLIA personnel requirements in subpart M have affected the health system's response to the COVID-19 PHE and any potential opportunities for improvement to such requirements. We welcomed suggestions regarding potential improvements that may be specific to a pandemic or PHE context, as well as broader recommendations.

1. Definitions (§ 493.2)

a. Mid-level practitioner

At § 493.2, we proposed amending the definition of midlevel practitioner by adding a nurse anesthetist and clinical nurse specialist to the definition. CLIA currently defines a midlevel

practitioner as a nurse midwife, nurse practitioner, or physician assistant. We stated in the proposed rule that we agree with CLIAC's recommendation to include nurse anesthetists and clinical nurse specialists in the definition of midlevel practitioner. We believe including nurse anesthetists and clinical nurse specialists in the definition will be inclusive of current types of mid-level practitioners. For example, the American Association of Nurse Anesthetists[17] scope of practice states that the practice may include performing point-of-care testing.

We received public comments on this proposed definition. The following is a summary of the comments we received and our responses.

Comment: A commenter expressed concern about updating the midlevel practitioner definition to include registered nurse anesthetists and clinical nurse specialists to be considered mid-level practitioners in the laboratory testing scope. The commenter noted that MTs have more courses designed to prepare them to work in a laboratory setting as compared to nursing students.

Response: The definition of a midlevel practitioner only applies to a site with a Certificate for Provider-performed Microscopy Procedures. PPM procedures, as described under § 493.19, are a select group of moderately complex microscopic tests that do not meet the criteria for waiver because they are not simple procedures; they require training and specific skills for test performance, and they must meet certain other standards. Since these procedures are performed at the time of a physician office visit, including registered nurse anesthetists and clinical nurse specialists as part of the definition of a midlevel practitioner allows greater access to PPM testing. The curriculum for the midlevel practitioners including RNAs and CNSs covers this type of testing.

After consideration of public comments, we are finalizing the proposed definition of "midlevel practitioner."

b. Continuing education (CE) credit hours

[17] *https://www.aana.com/.*

At § 493.2, we proposed adding a definition for "Continuing education (CE) credit hours" to state that it means either continuing medical education (CME) or CE units. Generally, CME refers to continuing education credits earned by physicians (by which we mean doctors of medicine, osteopathy, or podiatric medicine). We proposed that CE would be a broader term used for individuals seeking to qualify as LDs who are not physicians. We noted that in the current CLIA regulations at § 493.1405(b)(2)(ii), CME is considered as acceptable training or experience for individuals to qualify as a LD overseeing moderate complexity testing.

We stated in the proposed rule that because we were proposing in section III.B. of the proposed rule to require all individuals seeking to qualify as a LD for both moderate and high complexity testing to have 20 CE credit hours, we believed we needed to establish a more general term for purposes of the proposed requirement. As described below, the CE credit hours would cover all of the LD responsibilities defined in the applicable regulations and must be obtained prior to qualifying as a LD. For example, we proposed at § 493.1405(b)(2)(ii)(B), the 20 CE credit hours would be required to cover all of the LD responsibilities defined in § 493.1407 (moderate complexity testing).

The term CME was originally used because it was only required at § 493.1405(b)(2)(ii)(B), which is a provision specifically related to doctors of medicine, osteopathy, or podiatry. We believe that including a definition for CE credit hours in the CLIA regulations will respect that historic use, afford a means of referring to a broader range of professionals who may qualify as LDs, and alleviate confusion between the terms.

We received public comments on this proposed definition. The following is a summary of the comments we received and our responses.

Comment: A commenter noted that organizations provide CME for physicians that the Accreditation Council for Continuing Medical Education (ACCME) approves as CME providers. The commenter stated that CME programs are subject to strict rules about conflict of interest, commercial interests, and course design, which includes learning objectives. The commenter

suggested that the definition of CE credit hours be modified to meet equivalent or similar standards as CME.

Response: The proposed definition of CE credit hours under § 493.2 includes CME as a CE option. As previously discussed, the term CME was originally used because it was only required at § 493.1405(b)(2)(ii)(B), which is a provision specifically related to doctors of medicine, osteopathy, or podiatry. We proposed and are now finalizing a continuing education requirement for non-physician LDs who do not have an earned doctoral degree in biology, chemistry, clinical or medical laboratory science or medical technology. Because the term CME generally refers only to continuing education credits earned by physicians, we are finalizing a broader term, CE, which is defined to include either CME or CEUs. CLIA regulations do not regulate either CME or CE providers regarding conflict of interest, commercial interests, and course design, which includes learning objectives. CLIA regulations do however require that to be qualified as an LD, the candidate must obtain CME credits, or under this final rule CE credits, which cover all of the LD responsibilities defined in the applicable regulations.

After consideration of public comments, we are finalizing the proposed definition of "continuing education (CE) credit hours" without modification.

c. Doctoral degree

At § 493.2, we proposed adding a definition for "doctoral degree" to state that it means an earned post-baccalaureate degree with at least 3 years of graduate level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology. Originally, degrees were given in medical technology; however, the naming convention for medical technology degrees has changed since the regulations were first published in the February 1992 final rule with comment period. We stated in the proposed rule that the degree is now referred to as clinical laboratory science and that a clinical laboratory science degree is synonymous with a medical technology degree. For purposes of 42 CFR part

493, doctoral degrees would not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatry, doctors of veterinary medicine (DVM), or honorary degrees.

We proposed this modification to CLIA regulations to clarify what we mean by the term "doctoral degree." It seems this general term has created confusion as various interested parties have inquired about the following.

- Are doctors of medicine degrees considered to be a type of doctoral degree?
- Does a doctoral degree include traditional (for example, Doctor of Philosophy (PhD), doctorate in science (DSc) and professional (for example, Doctorate in Clinical Laboratory Science (DCLS)) degrees or does doctoral degree only mean a PhD?

The CLIA regulations for personnel qualifications separate doctors of medicine, osteopathy, and podiatry from other non-medical doctoral degrees by including specific qualification requirements for these three types of degrees. MD and DO degrees pertain to post-graduate level education, specifically in medicine, and are associated with treating illnesses and medical conditions. In contrast, doctoral degrees can be obtained in various fields like biology and chemistry. Historically, we intended a doctoral degree to mean a PhD in a science field related to laboratory work. However, we have come to understand that our doctoral degrees could be interpreted more broadly to include both traditional and professional doctoral degrees. Doctoral degree is a general term used to describe post-graduate level education for various non-medical specific degrees and includes both traditional (for example, PhD, DSc) and professional (for example, DCLS) degrees. A traditional earned doctoral degree is generally focused on research and may include academic coursework and professional development. In contrast, a professional earned doctoral degree emphasizes specific skills and knowledge for success in a particular profession without a concentrated focus on research. For example, the DCLS is an advanced professional doctorate designed for practicing clinical laboratory scientists (CLSs) or medical technologists (MTs) who have at least a bachelor's degree and wish to further their level of clinical expertise and develop leadership and management skills. Individuals with a DCLS are

experts in clinical laboratory testing. Individuals must have a bachelor's degree in medical technology or clinical laboratory science and the requisite experience in order to be admitted to a DCLS graduate program. The DCLS contributes to increasing laboratory efficiency and improves timely access to accurate and appropriate laboratory information. A graduate of a DCLS program will be able to: provide appropriate test selection and interpretation of test results; monitor laboratory data and testing processes; improve the quality, efficiency, and safety of the overall diagnostic testing process; and direct laboratory operations to comply with all State and Federal laws and regulations. We would consider a DCLS an acceptable doctoral degree.

For the purposes of qualifying under the CLIA personnel regulations, we do not consider a MD or DO to be the same as a non-medical doctoral degree. Therefore, these individuals must continue to qualify under the applicable CLIA personnel regulations, that is, MDs and DOs must qualify under doctors of medicine or osteopathy requirements. Those individuals with non-medical doctoral degrees as outlined previously in this final rule must qualify under the doctoral degree requirements. We stated in the proposed rule that if finalized, the State Operations Manual (SOM)[18] will be updated accordingly.

The CLIA regulations aim to ensure accurate and reliable testing on specimens derived from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health of human beings. Therefore, we stated in the proposed rule that we believe that DVM should be removed from the qualifying doctoral degrees as it is not relevant to testing on specimens derived from the human body. We understand many of the methodologies may be the same; however, testing on human specimens is clearly specified in the statutory language and regulatory definition of a laboratory under CLIA. Therefore, testing of animal specimens does not meet the intent of the CLIA regulations. Of the nine boards approved by HHS for qualification of applicants with doctoral degrees, only one allows individuals with DVMs to sit for board certification. Since 1965,

[18] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107c06pdf.pdf.*

American Board of Medical Microbiology has granted certification to four individuals. We stated that individuals who have previously qualified under a provision requiring a doctoral degree will continue to qualify under the new rule, if finalized. We further stated that if finalized, we would remove the reference to DVMs in the SOM, Chapter 6 (that is, Interpretive Guidelines) under § 493.1443(b)(3) (page 353).

Finally, as discussed previously in this rule, we proposed that a doctoral degree must be an earned post-baccalaureate degree with at least 3 years of graduate level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology. As such, honorary degrees do not meet the intent of a qualifying doctoral degree as an individual has not completed the necessary course and laboratory work required for the post-baccalaureate degree or necessary to ensure quality testing, for example, accurate and reliable results. We believe that qualifying individuals who hold only honorary degrees is not consistent with the public health purposes of the CLIA statute. Furthermore, we believe that this would impede CMS' ability to ensure health and safety of the public and individuals served by CLIA-certified laboratories.

We received public comments on this proposed definition. The following is a summary of the comments we received and our responses.

Comment: Several commenters referenced the 2022 decision by the American Medical Technologists (AMT), ASCP, and the American Society for Clinical Laboratory Science (ASCLS) to change the MT certification designation to Medical Laboratory Scientist (MLS). The commenters stated that this change recognizes the specialized expertise that the medical laboratory scientist brings to the practice of healthcare diagnostics, which needs to be adequately reflected in the term 'technologist.' The commenters suggested that medical laboratory science should be used in addition to clinical laboratory science in the proposed definition of doctoral degree under § 493.2.

Response: We agree with the commenters that medical laboratory science should be included in the definition of a doctoral degree, aligning with the 2022 decision to rename MT to MLS to elevate the visibility of the laboratory field. As a result, we have incorporated the change suggested by the commenters to include medical laboratory science in addition to clinical laboratory science in the finalized definition of doctoral degree at § 493.2, and elsewhere in these finalized regulations, where applicable, as discussed later in this final rule.

Comment: A commenter expressed concern about the proposed definition of a doctoral degree, stating that many LDs with PhD degrees come from a basic science background. These degrees require laboratory experience, yet that experience may not be related to clinical laboratory testing or clinical laboratory science. The commenter stated that qualification to direct a clinical laboratory is ensured by requiring board certification. The commenter believed that limiting permissible doctoral degrees to those relating directly to medical or clinical laboratory science would eliminate the vast majority of the candidate pools many fellowship programs draw from.

Response: We disagree with the commenter. The revised LD qualifications for moderate (§ 493.1405) and high (§ 493.1443) complexity testing expand the LD candidate pool in two ways. One, while we have removed physical science as a qualifying degree, we are adding two new degree types: medical laboratory science and medical technology. Two, if individuals hold non-qualifying degrees, they now have the opportunity to qualify under the new educational pathways. The CLIA regulations ensure accurate and reliable testing on specimens derived from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health of human beings. We believe that the inclusion of research related to clinical laboratory testing or advanced study in clinical laboratory science, medical laboratory science, or medical technology in the doctoral degree definition, as well as the additional educational option, encompasses the need to ensure

that LDs complete the required course and laboratory work to ensure quality testing for accurate and reliable results.

Comment: Several commenters disagreed with the proposed removal of the DVM degree from the qualifying doctoral degrees. Commenters stated that during the COVID-19 PHE, veterinary diagnostic laboratories (VDLs) were a significant resource capable of conducting critical public health diagnostic and surveillance testing. The commenters stated that VDLs conducted millions of tests that might otherwise not have been run. Commenters further stated that in some States, the VDL response capability and capacity served as the primary COVID-19 testing resource. However, they asserted that incorporating this valuable resource into the PHE response was often significantly delayed due to the inflexibility regarding recognizing VDL staff's training, knowledge, and experience as equal to that mandated under CLIA. Another commenter indicated that directors of VDLs are board certified in their specialties and often have PhDs in addition to their DVMs. There were additional commenters that supported the removal of a DVM degree from the qualifying doctoral degrees.

Response: Based on the critical role veterinary facilities provided in rapidly increasing testing capacity during the COVID-19 PHE, we believe it is appropriate to include DVMs during PHEs and may consider extending that flexibility in future PHEs. However, for the reasons previously discussed, these degrees would not be included as qualifying doctoral degrees outside of a PHE. Personnel with DVM degrees may qualify through the other routes indicated in subpart M. In addition, any individual with a DVM who is qualified and employed as an LD as of the effective date of this final rule will be grandfathered and continue to qualify as outlined in the grandfather provisions discussed elsewhere in this final rule, provided the individual remains continuously employed as an LD after the effective date.

After consideration of public comments, we are finalizing the proposed definition of "doctoral degree", with modification to include medical laboratory science. We are also

modifying “doctors of podiatry” to “doctors of podiatric medicine (DPM)” to be consistent with current regulations.

d. Training and experience

At § 493.2, we proposed to add a definition for “Laboratory training or experience” to state that it means that the training or experience must be obtained in a facility that meets the definition of a laboratory under § 493.2 and is not excepted from CLIA under § 493.3(b). Laboratory subject to CLIA would mean the laboratory meets the definition of a “laboratory” under § 493.2. Training and experience obtained in a research laboratory that only reports aggregate results or a forensic laboratory does not meet this definition. These types of facilities are exempt from CLIA under § 493.3(b), and as such, training and experience acquired in these facilities is not applicable to CLIA laboratories.

In all situations, an individual is required to meet training and/or experience requirements in addition to the educational requirements to competently perform their regulatory responsibilities. Because the CLIA personnel requirements for nonwaived testing are based on the complexity of testing performed (moderate versus high), we concluded that appropriate training and experience is necessary. Comments from the 2018 RFI support this proposal. Comments received from the 2018 RFI include the following:

- Training and or experience should be in a CLIA certified laboratory.
- Research experience is not equivalent to clinical experience.
- Dependent on complexity level of testing, minimum standards should increase as the complexity level increases.

Further, commenters stated that documentation from a former employer would be acceptable, provided it included specific details of the individual’s job description, training and competency assessment (CA) for areas of testing performed. This documentation could be from an LD, manager or supervisor.

We concur with the CLIAC recommendation, and comments from the 2018 RFI that all personnel should have training and experience in their areas of responsibility as listed in CLIA for the appropriate test complexity as shown in Table 8, which shows the specific personnel categories that have a provision requiring training or experience, or both, or require experience directing or supervising, or both.

TABLE 8: Personnel Requirements by Test Complexity for Proposed Personnel Changes that Require Training or Experience, or Both

CLIA Section	Role	Complexity
§ 493.1405	Laboratory director	Moderate
§ 493.1411	Technical consultant	Moderate
§ 493.1423	Testing personnel	Moderate
§ 493.1443	Laboratory director	High
§ 493.1449	Technical supervisor	High
§ 493.1489	Testing personnel	High

This means personnel should have training or experience examining and performing tests on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring an individual's condition.

Each individual must have documentation of training or experience applicable to the types and complexity of testing performed. This training should be such that the individual can demonstrate that he or she has the skills required for the proper performance of pre-analytic, analytic, and post-analytic phases of testing. For example, if the individual performs blood gas testing on a nonwaived point of care device, demonstration of skills should include, but is not limited to, the following:

- Proper specimen collection, handling and labelling;
- Proper test performance according to the laboratory's policies and manufacturer's instructions;
- Verification of performance specifications;
- Calibration and preventive maintenance;
- Proficiency testing; and
- Proper reporting of patient test results.

Training may include, but is not limited to, attendance at:

- Seminars given by experts in the field;
- On-site or off-site instrument trainings given by a manufacturer;
- Technical training sessions, workshops, or conferences given by a professional laboratory organization; or
- A formal laboratory training program.

Documentation may consist of, but is not limited to:

- Letters from training programs or employers;
- Attestation statements of an individual's training and experience by the LD;
- Log sheet(s) initialed by the attendees indicating attendance at a training session or in-service; and
- Certificates from organizations providing the training session, workshop, conference, specialty course.

We expect all documentation supporting an individual's education, training and experience to be independently generated, that is, not authored by the individual who is trying to meet CLIA personnel qualification requirements. For example, a curriculum vitae (CV) is not acceptable verification, in and of itself, to document an individual's education, training or experience. Letters on letterhead from previous employment, competency assessment, and comprehensive list of job responsibilities may be examples of acceptable documentation.

Laboratory testing of non-human specimens is not acceptable experience, for example, environmental, animal testing, as it is not used for the purpose of providing information used in the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

Comments received on the 2018 RFI stated that experience from a research laboratory should not be accepted. Depending on the circumstances, research testing can be either exempt from CLIA or subject to CLIA. Specifically, research laboratories that test human specimens but

do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients, are excepted from the CLIA regulations at § 493.3(b)(2). In accordance with that regulation, only those facilities performing research testing on human specimens that do not report patient-specific results may qualify to be exempt from CLIA certification.[19] An example of a non-patient-specific result would be "10 out of 30 participants were positive for gene X." The result in this example is a summary of the group data and is not indicative of an individual's health. An example of a patient--specific result would be "participant A was positive for gene X" in which the result is specific to participant A. In cases where patient -specific test results are maintained by a statistical research center for possible use by investigators in which the results are not reported out as patient-specific and could not be used "for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings," CLIA would not apply.

Research testing where patient-specific results are reported from the laboratory, and those results will be or could be used "for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" are subject to CLIA. Therefore, we would consider research experience related to reporting patient-specific results as applicable experience to meet the CLIA personnel requirements; however, if the research experience only included aggregate reporting of results, we would not consider this acceptable experience to meet CLIA personnel requirements as this type of research testing is exempt from CLIA (§ 493.3(b)(2)).

CLIA regulations at § 493.3(b)(1) specifically exempt facilities or components of facilities that only perform testing for forensic purposes from CLIA requirements. This was addressed in a Survey and Certification policy memo (S&C-08-35) published on September 5, 2008 (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html*). (See

[19] *https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/Research-Testing-and-CLIA.pdf.*

the preamble to the February 1992 final rule with comment period for an important discussion concerning this subject (57 FR 7014)).

In summary, laboratory results generated purely for the purpose of detecting illegal substances or illegal amounts of certain substances in the body may be relevant to legal proceedings. However, there is no concern in such testing for developing accurate and reliable data for use by health care professionals for the purpose of diagnosis or treatment. The determining factor is not the test itself, but the purpose for which the test is conducted.

In addition, based on the CLIA law, forensic testing is excluded under CLIA since forensic testing is conducted to determine if there has been a violation of the law and is not done for the purpose for providing diagnosis, treatment or assessment of health.

Therefore, we do not consider forensic testing to be an acceptable experience or training to meet CLIA personnel requirements as this type of testing is exempt from CLIA (§ 493.3(b)(3)).

We received public comments on this proposed definition. The following is a summary of the comments we received and our responses.

Comment: A commenter suggested expanding the definition of laboratory training or experience to allow research staff to qualify as laboratory testing personnel.

Response: The CLIA statute [20] defines a laboratory as a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. Laboratories that are performing research only (and do not report patient specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings)

[20] *https://www.govinfo.gov/content/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap6A-subchapII-partF-subpart2-sec263a.pdf.*

are not subject to CLIA regulations. Personnel with experience in a research laboratory may qualify under the methods listed under CLIA subpart M - Personnel for Nonwaived Testing.

After consideration of public comments, we are finalizing the proposed definition of "laboratory training or experience" without modification.

e. Experience directing or supervising

At § 493.2, we proposed adding a definition for "Experience directing or supervising" to state that it means that the director or supervisory experience must be obtained in a facility that meets the definition of a laboratory under § 493.2 and is not excepted under § 493.3(b). Experience directing or supervising a research laboratory that tests human specimens but does not report patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients would not meet this definition (for example, reporting of aggregate results). Experience directing or supervising any facility or component of a facility that only performs testing for forensic purposes also would not meet this definition. The ordering of tests and interpreting and applying the results of these tests in diagnosing and treating an individual's illness would not meet this definition because it is not related to the performance of clinical laboratory testing. Ordering of tests and interpreting and applying of results falls under the practice of medicine and are not related to the performance of clinical laboratory testing. Teaching experience directly related to a medical technology or clinical laboratory sciences program, or a clinical laboratory section of a residency program, would be considered acceptable experience because we understand that such experience from teaching related to a medical technology or clinical laboratory sciences program would include all aspects of the entire testing process (pre-analytic, analytic and post-analytic), as well as quality control and quality assessment. These are critical responsibilities of a LD as defined by CLIA. See discussion on proposed definition of "Laboratory training or experience" for more information on proposed treatment of research laboratories and forensic testing experience.

We did not receive public comments on this proposed definition for "Experience directing or supervising" and are finalizing as proposed.

2. PPM laboratory director responsibilities (§ 493.1359)

At § 493.1359, we proposed clarifying the competency assessment (CA) requirements for PPM laboratories in the Standard for PPM LD responsibilities, as this testing is moderate complexity per § 493.19(b)(2) and subject to CA. Based on the fact the regulations do not have a requirement for a TC for PPM laboratories, we believe that it is currently unclear in the regulation how CA applies to these types of laboratories. The SOM, Appendix C (that is, Interpretive Guidelines) on page 151 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf*) discusses CA for PPM laboratories. Therefore, we proposed clarifying, via modifications to this LD responsibilities section of the regulations, the CA requirement for PPM laboratories. We proposed that the LD evaluate the competency of all TP to ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. This would include the following:

- Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing;
- Monitoring the recording and reporting of test results;
- Review of test results or worksheets;
- Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and
- Assessment of problem solving skills.

Generally, these requirements mirror the CA provisions for moderate and high complexity testing at §§ 493.1413(b)(8) (technical consultant responsibilities) and 493.1451(b)(8) (technical supervisor responsibilities). We did not propose to include "Direct observation of performance of instrument maintenance and function checks" as the only

equipment required for PPM testing is limited to bright-field and phase-contrast microscopy. Typically, TP do not perform these activities for PPM testing; rather, they are performed by third-party entities.

In addition, we proposed at § 493.1359(d) the same CA intervals as in §§ 493.1413(b)(8) and 493.1451(b)(8) apply to mid-level practitioners for consistency. That is, evaluating and documenting the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually.

We received public comments on these proposals at § 493.1359. The following is a summary of the public comments we received and our responses.

Comment: A commenter suggested that TCs be allowed to perform PPM procedure CA. The commenter noted that TCs are not defined in the CLIA regulations but believes they are qualified to conduct CA for PPM procedures. The commenter also stated that allowing TCs to perform competency assessments would facilitate flexibility in meeting this requirement and reduce the burden on the LD.

Response: Testing sites that hold a CLIA Certificate for Provider-performed Microscopy Procedures are subject to CLIA personnel regulations for the laboratory director (§§ 493.1355, 493.1357, and 493.1359) and testing personnel only (§§ 493.1361, 493.1363, and 493.1365). CLIA does not have a personnel category for TC in PPM personnel requirements. The proposed CA provisions for LD of a PPM certificate mirror the CA provisions for moderate complexity testing at § 493.1413(b)(8) (TC responsibilities). If a CLIA CoC or CoA laboratory performs PPM procedures, then that laboratory is subject to all CLIA regulations related to moderate complexity testing. In those laboratories with a CoC or CoA, a TC can perform CA for moderate complexity testing including PPM procedures under § 493.1413(b)(8). However, in a CLIA certificate for PPM, it will be the LD's responsibility to perform CA.

Comment: A commenter suggested reducing the frequency of conducting the CA of individuals responsible for PPM testing to every 2 years rather than annually. The commenter noted that PPM testing is often performed by physicians or licensed providers with advanced degrees and extensive training who are highly engaged in the clinical situations where they are conducting the testing.

Response: PPM testing is moderate complexity per § 493.19(b)(2). The proposed CA intervals were kept the same as those for moderate and high complexity for consistency.

Comment: A commenter supported requiring PPM LDs to undergo CAs at the same interval as moderate and high complexity laboratories. The commenter stated that since PPM laboratories are not inspected regularly, there currently needs to be a mechanism for State agencies to monitor CA activities to ensure compliance. The commenter suggested that CMS devise and implement reporting requirements and inspection methods for PPM laboratories.

Response: CLIA Certificate for PPM Procedure laboratories must meet the applicable requirements for inspection under subpart Q of the CLIA regulations. We further note that reporting and inspection requirements are outside the scope of this rule.

In the proposed rule, we used the following terms to refer to the provider-performed microscopy procedure certificate: Certificate for Provider Performed Microscopy Procedures (PPMP), Certificate of Provider Performed Microscopy (PPM), and Certificate for Provider Performed Microscopy (PPM). For internal consistency, we are updating these terms in this section and throughout this final rule to "Certificate for Provider-performed Microscopy (PPM) Procedures" when referring to the provider-performed microscopy procedures certificate.

We also note that in this final rule, CMS is making technical changes to proposed section § 493.1359(d) to enhance consistency.

After consideration of public comments, we are finalizing the changes to § 493.1359 as proposed, with modification for internal consistency at § 493.1359(d).

3. Laboratory director qualifications (§ 493.1405)

At §§ 493.1405(b)(1)(ii), 493.1411(b)(1)(ii), 493.1443(b)(1)(ii), and 493.1449, we proposed removing "or possess qualifications that are equivalent to those required for such certification." In making this proposal, we acknowledge that there are limited timeframes for an individual to sit for the boards, however, by allowing any such "eligible" individual to qualify under our regulations, we have found that some individuals may never sit for exams or may even fail the exams. Such individuals were not who we intended to be eligible under these provisions. Further, even if we were to ban such individuals by carving them out of those we considered to hold "qualifications that are equivalent to those required for certification," it would be difficult to identify those individuals and remove them from their LD roles. In making this proposal, we acknowledged having historically accepted letters from individuals that have documented proof from the American Board of Pathology or American Board of Osteopathic Pathology that they are eligible to sit for the boards based on SOM guidance (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf,* page 351, D6078). In addition, we proposed eliminating the equivalency standard, as we do not have a means to evaluate equivalency to other boards for equivalency to American Board of Pathology or American Board of Osteopathic Pathology as it would be up to the Board to make a determination of equivalency, and we do not believe in retrospect it would be appropriate to expect those entities to conduct such analyses. Furthermore, we had requested that CLIAC consider what "possessing qualifications that are equivalent to board certification" should mean. CLIAC recommended that this verbiage be removed from relevant sections of subpart M because it was confusing, and we have no mechanism to determine when qualifications are "equivalent to board certification." We concur with the CLIAC recommendation. Further, we believe that individuals who historically may have qualified under this provision would still qualify through alternative routes, thus not disadvantaging individuals seeking to qualify as LDs. We further proposed that an individual who qualified under the predecessor regulations and is currently employed as a LD may continue to serve in that capacity so long as there is no break in service after the effective date of this final

rule. For example, an individual who is serving as the LD of a CLIA-certified laboratory at the date of the publication of the final rule, and continues to serve as a LD of CLIA-certified laboratory that performs nonwaived testing, would continue to qualify. However, an individual who does not continue as LD of a CLIA-certified laboratory after the date of implementation of the final rule would need to requalify under the new provisions.

At § 493.1405(b)(2)(ii)(A), we proposed changing the "or" to an "and" to include directing or supervising nonwaived laboratory testing in the provision. In addition, we proposed to remove "Beginning September 1, 1993" from § 493.1405(b)(2)(ii)(B) and continue to retain the provision for 20 hours of CE credit hours for moderate complexity LDs who are seeking to qualify without certification by the American Board of Pathology and the American Board of Osteopathic Pathology. We believe by requiring the 20 CE credit hours, the LDs would have a better understanding of their responsibilities in the overall management and direction of laboratories, which would result in improved overall compliance. Historically, LD citations are among the top 10 condition-level deficiencies cited by surveyors. We believe that this would also improve the ability of laboratories to report accurate and reliable test results, thus helping to protect the health and safety of the public.

At §§ 493.1405(b)(2)(ii)(C) and 493.1443(b)(2)(i), we proposed removing the residency provision for the following reasons. First, the residency requirement causes confusion with board certification for doctoral degrees (for example, American Board of Internal Medicine). It is also challenging for these individuals to qualify under this provision as the medical residencies generally do not include the type of laboratory training or require the 1 year of laboratory training that we would expect to see related to laboratory administration and operation for which the LD is responsible. We would expect the residency program to provide an individual with essential information regarding the principles and theories of laboratory practice, including quality control and quality assessment; proficiency testing; the phases of the total process (that is, pre-analytic, analytic, and post-analytic), as well as general laboratory systems; facility

administration; and development and implementation of personnel policy and procedure manuals. This training should also include hands-on laboratory testing. However, a typical residency does not include a year of laboratory training (defined in interpretive guidelines as 2,080 hours of laboratory training) nor does it include essential information on the principles and theories of laboratory practice. We have observed, and AOs have noted to us, that very few individuals qualify through the medical residency route. The onus for providing the documentation related to clinical laboratory experience during residency is on the applicants (that is, the applicants must document their clinical laboratory experience during residency).

CLIAC recommended that we clarify the residency requirements by emphasizing the requisite laboratory training must be "clinical laboratory training," meaning "have at least one year of clinical laboratory training during medical residency or fellowship." However, we believe that 1 year of laboratory training is vague. We also believe that after removing the residency requirement, there would be several alternative routes for individuals to qualify as LDs. Individuals seeking to qualify as a moderate complexity LD may still qualify under § 493.1405(b)(3) through (5) without a medical residency. We would continue to accept residency experience as counting toward the requirement of 2 years of laboratory experience directing or supervising high complexity testing for doctors of medicine, doctors of osteopathy, or doctors of podiatry. We would also accept experience directing or supervising high complexity testing from a medical fellowship program toward the requirements outlined in the regulations. Generally, a fellowship program follows a residency program and is for those individuals who choose to pursue additional training in their specialty. Section 493.1443(b)(2)(ii) is the current requirement that allows individuals with at least 2 years of experience directing or supervising high complexity testing to qualify under paragraph (b)(2).

At § 493.1405(b)(3), we proposed revising paragraph (b)(3)(ii) to include an educational option that includes a qualification algorithm for an individual that does not have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology

(see section I.D.1.a of the proposed rule). We also proposed adding paragraph (b)(3)(iii) to include the addition of 20 CE credit hours for doctoral degrees, as well as the current paragraphs (b)(3)(i) through (ii). This would include the requirement to be certified by an applicable board and continue to be certified and have at least 1 year of experience directing or supervising nonwaived testing. (As discussed later in this section of the final rule, these provisions in the proposed rule at § 493.1405(b)(3) are being reformatted and finalized at the revised (b)(3)(i) through (ii).)

The current CLIA regulations at §§ 493.1405, 493.1411, 493.1423, 493.1441, 493.1449, 494.1461, and 493.1489 indicate acceptable degrees for personnel as those in a chemical, physical, biological science, or clinical laboratory science or medical technology. Degree names and types have changed since the CLIA regulations were first published in 1992. As a result, in some cases, there are degrees for which the area of study may not be clear based on the name of the degree given. This makes it challenging for CMS, State agencies, Exempt States (ES), and AOs to determine what types of degrees are considered acceptable degrees in order to qualify CLIA personnel. At the time the CLIA regulations were published, individuals typically received a degree in the areas of biology, chemistry, medical technology, or clinical laboratory science. Today, we often must perform an evaluation of transcripts to determine if the individuals meet CLIA personnel requirements.

We believe it is important that individuals lacking a traditional degree in chemical, biological, or clinical laboratory science or medical technology should be considered if they have completed the coursework that is equivalent to the aforementioned traditional degrees and acquired documentation of the equivalent educational coursework. In addition to the educational requirements discussed in this section, CLIA also has experience and training requirements (see our proposed updates to §§ 493.1405, 493.1411, and 493.1423), but they will not be addressed in this educational discussion.

We believe degrees should be in a science that deals in the kind of clinical laboratory testing, that is related to testing of human specimens as the definition of a "laboratory," which is defined in terms of the examination of materials from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings (see § 493.2). In some cases, it is clear that a degree would meet these standards. For example, degrees in microbiology, genetics, molecular biology, biochemistry, and organic chemistry would be considered appropriate degrees. In other instances, it is not apparent whether the degree would meet such requirements. Environmental sciences, biotechnology, and marine biology are examples of degrees that would not appear in keeping with the scope of the CLIA program. At face value, we do not believe these types of degrees should qualify an individual under the requirements in subpart M because they are not related to clinical laboratory testing. Environmental science degrees may cover such areas as ecosystem management, the impact of industrialization on the environment, and natural resource management. Biotechnology degrees focus on developing technologies and products related to medical, environmental, and industrial areas. Marine biology focuses on studying marine organisms, their behaviors, and interactions with the environment. We would not consider these to be appropriate degrees under the CLIA program because these degrees do not generally appear to be focused on clinical laboratory testing or focused on the testing of human specimens, which is the scope of the CLIA regulations. However, in the proposed rule, we proposed an option for an educational algorithm based on semester hours (SH) as an alternative qualification mechanism. We stated in the proposed rule that if finalized, individuals with degrees that are not clearly biological or chemical in nature may be evaluated using this algorithm and may qualify for CLIA personnel positions in subpart M.

In developing the proposed algorithm, we explored the required courses for bachelor's, master's, and doctoral degrees in the major studies of biology, chemistry, and medical technology. For purposes of this discussion, only degrees in biology and chemistry will be

addressed, as degrees in medical technology and clinical laboratory science do not need to be evaluated for equivalency. Multiple sections of the CLIA regulations specify that educational degrees in "chemical, physical or biological science or medical laboratory technology from an accredited institution" constitute appropriate education to qualify for laboratory roles in the noted complexity and laboratory specialty areas. In all situations, the educational requirement is based on the laboratory individual having a sufficient educational background (coursework) to be qualified to gain the subsequent training and experience to competently perform their roles.

Three levels (small, medium, and large) of both public and private accredited universities and colleges were reviewed. For purposes of this research, small institutions were defined as less than 5,000 students, medium as 5,000 to 15,000 students, and large as greater than 15,000 students. Seven colleges and universities were evaluated for all three defined types. Table 9 describes the number of SH required across all three sizes of colleges and universities for both a bachelor's in Biology and a bachelor's in Chemistry.

TABLE 9: Average Required Semester Hours (SH)* for Bachelor's Degrees in Biology and Chemistry

Semester Hours (SH)	Bachelor's Biology	Bachelor's Chemistry
Biology SH	20-49	≥8**
Chemistry SH	8-20	25-56
Other (Includes biology/chemistry)	7-28	11-42

* Quarter hours may be converted to semester hours by multiplying the semester hours by 1.5. For example, 3 semester hours is equivalent to 4.5 quarter hours.
**The majority of colleges and universities did not break out the biology SH, but instead grouped them in "Other".

In general, accredited colleges and universities require general biology, molecular biology or genetics, general chemistry, organic chemistry, and biochemistry. We proposed a specific coursework algorithm to qualify candidates, in lieu of a qualifying degree, for all testing levels. At present, only § 493.1489(b)(2)(ii) specifies specific coursework required. This is for an associate degree individual to perform high complexity testing. Specifying coursework requirements will allow CMS, State agencies (SA), accreditation organizations (AO), and exempt States (ES) to consistently evaluate educational qualifications.

For both the doctoral degree and master's degree curricula, there were no consistent coursework, thesis or research requirements for Biology and Chemistry majors of study. For example, evaluation of the master's degree requirements revealed three tracks that included:

- Coursework;
- Coursework and thesis; and
- Coursework, thesis, and research.

For doctoral degrees, we proposed the following educational algorithm for those individuals who have a doctoral degree that is not clearly in a chemical or biological science. We stated that we would expect those individuals to:

- Meet master's degree equivalency; and
- At least 16 SH of additional doctoral-level coursework in biology, chemistry, medical technology, or clinical laboratory science; and
- A thesis or research project in biology, chemistry, medical technology, or clinical laboratory science related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of or the assessment of the health of human beings.

CLIAC recommended that other degrees (such as those in the humanities, physical sciences, and others) may not have the requisite science coursework, and candidates for positions should be considered based on a minimum number of hours of courses with laboratory components with relevance to clinical laboratory testing (which could also come from post degree curricular work). We concur with CLIAC's recommendation that relevant science and laboratory coursework should be considered when evaluating an individual's education qualifications.

The educational algorithm may allow individuals without a traditional chemical or biological degree to meet the CLIA personnel education requirements based on their coursework. Individuals who may have the appropriate coursework would not be disadvantaged by having a degree that is not considered chemical or biological in nature. Please note that the requirements

for the applicable laboratory training or experience, or both, found in subpart M (and discussed previously), are required in addition to the educational requirement.

At § 493.1405(b)(4), we proposed redesignating current paragraphs (b)(4)(ii) and (iii) as paragraphs (b)(4)(iv) and (v), respectively. We proposed new paragraphs (b)(4)(ii) and (iii) as additional educational options that include a qualification algorithm for an individual that does not have a master's degree in a chemical, biological, or clinical laboratory science or medical technology (see section III.B.3. of the proposed rule). We proposed adding a new requirement at paragraph (b)(4)(vi) to include the addition of 20 CE credit hours. (As discussed later in this section of the final rule, these provisions in the proposed rule at § 493.1405(b)(4) are being reformatted and finalized at the revised (b)(4)(i) through (iv)).

As a result of the above discussion, we proposed that individuals meet either of the following two options for use as educational algorithms:

- Option 1

++ Meet bachelor's degree equivalency; and

++ At least 16 SH of additional graduate level coursework in biology, chemistry, medical technology, or clinical laboratory science; or

- Option 2

++ Meet bachelor's degree equivalency; and

++ At least 16 SH, which may include a combination of graduate level coursework in biology, chemistry, medical technology, or clinical laboratory science and a thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

At § 493.1405(b)(5), we proposed redesignating current paragraphs (b)(5)(ii) and (iii) to paragraphs (b)(5)(iii) and (iv), respectively. In addition, we proposed a new paragraph (b)(5)(ii) with an educational option that includes a qualification algorithm for an individual that does not have a bachelor's degree in a chemical, biological, or clinical laboratory science or medical

technology (see section I.D.1.c. of the proposed rule). We also proposed adding a new requirement at paragraph (b)(5)(v) to include the addition of 20 CE credit hours. (As discussed later in this section of the final rule, these provisions in the proposed rule at § 493.1405(b)(5) are being reformatted and finalized at the revised (b)(5)(i) through (iv)).

In general, an associate degree requires the completion of 60 SH, and a bachelor's degree requires the completion of 120 SH. In the case of bachelor's degrees, for this reason, we proposed that the equivalent educational requirements for associate degrees at the existing § 493.1489(b)(2)(ii) should be doubled. That is, an individual must have at least 120 SH, or equivalent, from an accredited institution that, at a minimum, include either 48 SH of medical laboratory technology or clinical laboratory science courses; or 48 SH of science courses that include: 12 SH of chemistry, which must include general chemistry and biochemistry or organic chemistry; 12 SH of biology, which must include general biology and molecular biology, cell biology or genetics; and 24 SH of chemistry, biology, or medical laboratory technology or clinical laboratory science in any combination. (Note: We did not propose to amend the education SH requirements at the existing § 493.1489(b)(2)(ii) in the proposed rule, as there is no need to amend. However, in the proposed and now final rule, the existing § 493.1489(b)(2)(ii) is redesignated and reformatted as § 493.1489(b)(3)(ii)).

In addition to the degrees discussed previously in this rule, we proposed a new framework for evaluating non-traditional degrees, a part of the educational algorithm described previously. One example of a non-traditional degree may be a Regents Bachelor of Arts (RBA), which is a baccalaureate degree program designed for adult students. The basic principle of an RBA is that credit is awarded for what students know, regardless of how that knowledge was obtained. In other words, students may earn college equivalent credit for work and life experiences that can be equated to college courses. It is designed to provide students with a comprehensive general education. Many times, no specific courses are required for graduation, allowing students to design their own programs of study. This degree is usually awarded by a

Board of Regents. It is a general education degree without the designation of a major. Many of these individuals have an associate degree in medical laboratory technology (MLT), but not an appropriate bachelor's degree that would make them eligible to qualify under the provisions in CLIA personnel requirements that require a minimum of a bachelor's degree in specified scientific fields. This becomes problematic because the RBA does not designate a major. Generally, in these cases, we have seen that these individuals have an associate degree in MLT and have many years of clinical laboratory experience. Currently, these individuals cannot meet CLIA personnel qualifications in subpart M that require a minimum of a bachelor's degree. We believe that their education and experience should qualify them to be TCs as long as their associate degree is in medical laboratory technology or laboratory science. Public feedback from the 2018 RFI supported that a non-traditional degree should be considered as a means to meet CLIA requirements for the TC and TP for moderate complexity testing, provided a minimum number of SH were obtained in chemistry, biology, and laboratory sciences. We believe a non-traditional degree can be a means to qualify as TC and TP, provided an adequate number of biology, chemistry or medical laboratory, or clinical laboratory science courses is part of the curriculum in addition to meeting the training or experience requirements. However, we do not believe a nontraditional degree can be a means to qualify as a laboratory director.

At § 493.1405(b)(6) through (7), we proposed removing the "grandfather" provisions as these requirements had to have been met by February 28, 1992. Individuals can no longer qualify under these provisions. A grandfather is a provision in which a previous rule would continue to apply to individuals already qualified and employed in the given personnel capacity upon implementing a new rule. The new rule will apply to all individuals seeking to qualify after the implementation of said rule. We proposed to revise paragraph (b)(6) with a new grandfather provision for all individuals who qualified under this provision, as well as § 493.1406, prior to the date of the final rule. We stated in the proposed rule that we intend to allow individuals already qualified and employed in the given personnel capacity as of the date of the final rule to

continue to be qualified under the new provisions (that is, grandfathered). However, we stated that we intend to require all individuals becoming employed by a laboratory or changing assignments within a laboratory after the final rule's effective date to qualify under the new provisions. This includes those individuals who may have been previously employed in a given position prior to the effective date but took a break or a leave of absence and came back after the date of the final rule.

We received public comments on these proposed provisions at § 493.1405. The following is a summary of the public comments we received and our responses.

Comment: A commenter suggested a formal recognition of board certification in MT, CLS, MLS, and other subspecialties instead of qualifications based on coursework. The commenter added that accreditation organizations need to recognize board certification because they are not required in the CLIA regulations. According to the commenter, those with ASCP and other certifications are higher qualified laboratory scientists who meet the CLIA minimum. The commenter further stated that it is often easier to obtain certification verification than to prove degree coursework, especially from schools or programs that no longer exist.

Response: We believe this type of documentation is not sufficient evidence of meeting the personnel qualifications. We have found that the certifying boards may certify individuals as MT, CLS, and MLS with a variety of degrees if they meet an educational algorithm. Their coursework may not meet the minimum CLIA personnel requirements, but there may be enough science classes to sit for the examination and be certified as an MT, CLS, or MLS. In addition, not all certifying boards have the same requirements for certification. We will continue requiring detailed information, such as degrees, transcripts, or Primary Source Verification (PSV) documents, to verify educational credentials per the policy memorandum, S&C: 16-18-CLIA (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-18.pdf*).

Comment: Several commenters noted the 2022 decision by AMT, ASCP, and ASCLS to change the MT certification designation to MLS. The commenters suggested that medical laboratory science should be used in addition to clinical laboratory science throughout the CLIA personnel qualifications.

Response: We agree with the commenters that medical laboratory science should be included in the revised personnel qualifications. We are incorporating the change suggested by the commenters where applicable in revised § 493.1405 and other applicable sections of subpart M.

Comment: Many commenters agreed with the removal of "physical science" as a degree. A commenter stated that defining specific courses of study which must be completed to qualify as a LD (that is, biochemistry or organic chemistry; molecular biology, cell biology, or genetics) unfairly discriminates against degree programs that impart the necessary knowledge to perform the duties of LD but do not include these specific courses. The commenter added that foreign and alternative degrees might also prepare a person to perform the LD duties better than degree programs that have those specific courses.

Response: We believe it is important that individuals lacking a traditional degree in chemical, biological, clinical, or medical laboratory science or medical technology should be considered if they have completed the coursework equivalent to the aforementioned traditional degrees and acquired documentation of the equivalent educational coursework. In response to the 2018 RFI (83 FR 1005 through 1006, 1008), commenters recommended that we evaluate coursework taken using an SH educational algorithm to qualify individuals for CLIA personnel positions. CLIAC also stated that degrees (such as those in the humanities, physical sciences, and others) might require the requisite science coursework. The courses indicated in the proposed algorithm meet the CLIAC recommendation for courses with laboratory components relevant to clinical laboratory testing.

Comment: A commenter opposed lowering of educational standards for LD and disagreed with the proposal to add a qualification pathway for moderate and high-complexity LD that includes an educational algorithm for an individual that does not have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology. The commenter suggested that a doctorate-level or medical doctor degree should be the minimum educational qualification for LD, given the importance of the role of overseeing the overall management and operations of the clinical laboratory.

Response: We agree that the doctoral degree algorithm requires, at a minimum, a doctoral degree and therefore are revising proposed § 493.1405(b)(3)(ii)(A) (finalized at § 493.1405(b)(3)(i)(B)) to specify that the individual must have an earned doctoral degree for purposes of the doctoral degree algorithm. However, we do not agree that LDs of a laboratory performing moderate-complexity testing require a doctoral degree. Since 1992 the CLIA LD qualifications for laboratories performing moderate complexity testing (§ 493.1405) have provided pathways for individuals with a master's or bachelor's degree to qualify as moderate complexity LD. The proposed moderate complexity LD qualifications for master's and bachelor's degrees courses indicated in the proposed algorithm meet the CLIAC recommendation for courses with laboratory components relevant to clinical laboratory testing.

In this final rule, consistent with our proposed and final policy, we are also reformatting proposed § 493.1405(b)(3) to clarify that both individuals qualifying with a traditional doctoral degree and those qualifying under the new educational pathway, must have the specified 20 CE credit hours, certification, and experience. As we explained in the July 2022 proposed rule (87 FR 44914), these requirements apply to individuals qualifying with doctoral degrees. We are also reformatting proposed § 493.1405(b)(4) and (5) to clarify that individuals qualifying with a traditional master's or bachelor's degree and those qualifying under the new educational pathway must all have the required laboratory training or experience and CE credits, as we discussed in the July 2022 proposed rule (87 FR 44915-44916).

Also at §493.1405(b)(4)(i)(C)(*2*) of this final rule we are revising to clarify that under this educational pathway, 16 semester hours in a combination of graduate level coursework in specified subjects and a thesis or research project related to CLIA laboratory testing is required. At the final regulations at both § 493.1405(b)(3)(i)(B)(*2*) and (b)(4)(i)(C)(*2*), we are clarifying that for those who qualify with a thesis or research project, that thesis or research project must be approved, meaning the individuals must have received credit for it as reflected on their transcript. CMS's policy is to verify educational qualifications by reviewing transcripts, as described in its Survey and Certification Memorandum 16-18-CLIA*, Personnel Policies for Individuals Directing or Performing Non-waived Tests* at 2-4 (April 1, 2016), available at *https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-to-states-and-regions-items/survey-and-cert-letter-16-18*.

We are also making technical changes in this section of the regulatory text in this final rule to enhance consistency.

After consideration of public comments, we are finalizing the proposed provisions at § 493.1405, with the following modifications:

- To specify at § 493.1405(b)(3)(i)(B) that for purposes of the doctoral degree algorithm, an individual must hold an earned doctoral degree,
- To reformat the regulations at § 493.1405(b)(3) through (5).
- To revise § 493.1405(b)(3)(i)(B)(*2*) and (b)(4)(i)(C)(*2*) as described previously.
- To include medical laboratory science in § 493.1405 where applicable.

4. Laboratory director qualifications on or before February 28, 1992 (§ 493.1406)

At § 493.1406, we proposed removing the grandfather provision for these requirements as they had to have been met by February 28, 1992. Individuals can no longer qualify under these provisions. We stated in the proposed rule that we plan to grandfather all individuals qualified

under this provision prior to the date of the final rule under § 493.1405(b)(6). All individuals qualifying after the date of the final rule will be required to qualify under the new provisions.

We received no public comments on this provision and are finalizing the proposed removal of § 493.1406.

5. Laboratory director responsibilities (§ 493.1407)

At §§ 493.1407(c) and 493.1445(c), we proposed revising the requirements so that the LD must be on-site at the laboratory at least once every 6 months, with at least a 4-month interval between the two on-site visits. However, LDs may elect to be on-site more frequently. The laboratory must provide documentation of these visits, including evidence of performing activities that are part of the LD responsibilities. We concur with CLIAC's recommendation that LDs should make at least two (reasonably spaced) on-site visits to each laboratory they direct per year. We stated that we would expect the on-site visits to be once every 6 months with an interval of at least 4 months between the two on-site visits. We will continue to require that the LD be accessible to the laboratory to provide telephone or electronic consultation as needed. Based on a review of information provided by State agencies, AOs, and ESs, onsite LD visits are required as follows:

- 19 percent (n=10 of 54), meaning 9 non-exempt States plus 1 territory require on-site visits out of 54 States and territories;
- 43 percent (n=3 of 7) AOs; and
- 50 percent (n=1 of 2) ES.

CLIA statistics show that LD citations are consistently among the top 10 condition level-deficiencies cited by surveyors.[21] Feedback from the States, AOs, and ES indicated that the number of deficiencies cited at the time of the survey was less when the LD was on-site full-time or made regular on-site visits. Based on anecdotal information from the State agencies, ES, and AOs, the laboratories that did not have a LD who made regular visits to the laboratory tended to

[21] *https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAtopten.pdf.*

have an increased number of citations related to overall noncompliance with laboratory requirements. Some States currently require on-site LDs to visit their laboratory at prescribed intervals, while others do not (see Table 10 for a complete list of States and territories). Feedback from States and AOs that did not have such a requirement for on-site visits, generally supported the addition of a requirement for on-site visits. Further, on-site visits are meant to supplement regular interactions between off-site directors and the lab (for example, by telephone or other telepresence). We concur with CLIAC's recommendations that clear documentation of LD on-site visits should demonstrate the laboratory is in continuous compliance with current laws and regulations, including but not limited to the assessment of the physical environment for safe laboratory testing. The on-site LD visits cannot be delegated. We believe adding the on-site requirement supports increased compliance for laboratories.

TABLE 10: State and Territorial Requirements for On-site Laboratory Directors Every 6 Months

Requirement for On-site Laboratory Directors Every 6 Months	Do not Require On-site Laboratory Directors Once Every 6 Months
Georgia Hawaii Maine Maryland Nevada New York* Oklahoma Pennsylvania Rhode Island Tennessee Puerto Rico (territory)	Alabama Alaska American Samoa (territory) Arkansas Arizona California Colorado Connecticut Delaware District of Columbia Florida Guam (territory) Idaho Illinois Indiana Iowa Kansas Kentucky Louisiana Massachusetts Michigan Minnesota Mississippi Missouri Montana North Carolina North Dakota Nebraska New Hampshire New Jersey New Mexico Ohio Oregon Saipan (territory) South Carolina South Dakota Texas Utah Vermont Virginia Virgin Islands (territory) Washington** West Virginia Wisconsin Wyoming
N=9 States + 1 US territory, 1 ES*	N=40 States,4 US territories, + District of Columbia, 1 ES**

We received public comments on these proposals at § 493.1407. The following is a summary of the public comments we received and our responses.

Comment: Several commenters requested clarification regarding the definition of a laboratory site visit. One commenter noted that there could be several physician offices, outpatient clinics, hospital rooms, operating rooms, and other settings performing moderate complexity testing under a single CLIA certificate. The commenter questioned if the LD on-site visit pertains to all locations under a single CLIA certificate or just a single site. Another commenter was concerned that the proposed language regarding LD site visit requirements does not exempt CLIA home office sites. The commenter stated that existing and proposed CMS regulations still consider CLIA home office sites as 'laboratories,' which is inconsistent with common sense definitions of the non-laboratory activities occurring at these locations and suggested that CMS update and streamline regulations to accurately reflect the minimal scope of activities occurring at these home office locations. Another commenter noted that no data nor statistics were provided to support the perception that clinical laboratories with more regular on-site LD presence have fewer quality issues or lower number of deficiencies than those with less on-site LD presence. The commenter requested flexibility concerning the timeframes for the proposed visits by the CLIA LD to each of the clinical laboratories and suggested one on-site visit for laboratories with a limited scope of specialties (three or less) and a low volume of tests (2,000 -10,000 per year), flexibility with the 4-month separation between 6-month visits, and allowance for virtual visits as an option also to meet the proposed requirement, which it stated would be economically and logistically beneficial.

Response: CLIAC recommended that LDs make at least two (reasonably spaced) on-site visits to each laboratory they direct annually. As noted in the proposed rule, some States require on-site LDs to visit their laboratories at prescribed intervals. In contrast, others do not, and feedback from States and AOs that did not have such a requirement for on-site visits generally supported the addition of a requirement for on-site visits. The on-site visit requirement pertains to only one location site visit per CLIA certificate. However, LDs may elect to be on-site more frequently. If a home office is used under the oversight of a primary laboratory CLIA certificate,

then that primary site's LD will determine if the home office should be included in the on-site inspection. If a home office holds its own CoC or CoA, the LD must inspect those sites at the frequency specified in this final rule.

Comment: A commenter requested clarification regarding the LD requirement to document the visits and include evidence of performing activities.

Response: As currently required by CLIA under § 493.1407(e), the LD must ensure that the laboratory is in continuous compliance with current laws and regulations. The documentation required in the final § 493.1407(c) must be sufficient for the LD to demonstrate compliance with this provision. The LD determines the type or process of documentation needed as evidence of performing visits. Documentation may include, but is not limited to, sign in/sign out logs, meeting minutes/summary, notes of observations, and travel vouchers.

After consideration of public comments, we are finalizing the proposed provisions at § 493.1407(c) without modifications.

6. Technical consultant qualifications (§ 493.1411)

As discussed in section III.B.3. of the proposed rule, we proposed to amend § 493.1411(b)(1)(ii) by removing "or possess qualifications that are equivalent to those required for such certification."

As discussed in section III.B.17. of the proposed rule, we proposed to amend § 493.1411(b)(3)(i) by removing an earned doctoral, master's, or bachelor's degree in "physical science" as a means to qualify. We further proposed to redesignate current paragraph (b)(3)(ii) as paragraph (b)(3)(iii). Then, we proposed to revise paragraph (b)(3)(i) by changing the "and" to an "or" and to add a requirement at new paragraph (b)(3)(ii) to meet either § 493.1405(b)(3)(ii) or (b)(4)(ii) or (iii) to allow individuals who do not have a chemical, biological, or clinical laboratory science or medical technology degree to be eligible to qualify as a TC using the educational algorithm. (As discussed later in this section of the final rule, these provisions in the proposed rule at § 493.1411(b)(3) are being reformatted and finalized at revised (b)(3)(i) and

(ii).)

As discussed in section III.B. 17 of the proposed rule, we proposed to revise § 493.1411(b)(4)(i) by removing a doctoral, master's, or bachelor's degree in "physical science" as a means to qualify, and adding an earned doctoral, master's, or bachelor's degree in "clinical laboratory science" as a means to qualify. At § 493.1411(b)(4), we proposed changing the "and" to an "or" in paragraph (b)(4)(i). We also proposed to redesignate current paragraph (b)(4)(ii) as paragraph (b)(4)(iii) and to add a new paragraph (b)(4)(ii) to state that the individual must meet the criteria in § 493.1405(b)(5)(ii) (finalized in this final rule at § 493.1405(b)(5)(i)(B)) to allow individuals who do not have a chemical, biological, or clinical laboratory science or medical technology degree to be eligible to qualify as a TC using the educational algorithm. We stated we would also redesignate the current § 493.1405(b)(5)(ii) as § 493.1405(b)(5)(iii) and added an "or" following proposed § 493.1405(b)(5)(i). (As discussed later in this section of the final rule, these provisions in the proposed rule at § 493.1411(b)(4) are being reformatted and finalized at the revised (b)(4)(i) and (ii).)

At § 493.1411(b), we proposed adding a requirement at paragraph (b)(5) to allow individuals with an associate degree in medical laboratory technology or clinical laboratory science and at least 4 years of laboratory training or experience, or both, in nonwaived testing and the designated specialty or subspecialty areas of service for which the TC is responsible for qualifying as TCs. As discussed in section I.B. of the proposed rule, CLIAC recommended that we modify CLIA requirements to add the option for individuals with an associate degree to qualify as TCs. We concur with the CLIAC recommendation. In general, this will allow individuals who may have an applicable associate degree in addition to required training or experience, or both, to qualify as TCs. We recognize that the current personnel qualifications for general supervisors (GS) for high complexity testing may be less stringent than those of TCs for moderate complexity testing. The current CLIA regulations allow an individual with an associate degree (§ 493.1461) to perform CA on high complexity TP (see §§ 493.1461(c)(2),

493.1489(b)(2)(i)). The regulations under moderate complexity state that the TC is responsible for CA and does not allow delegation of this responsibility to any individual. The high complexity regulations allow the LD or TS to delegate the CA to the GS. However, the same individual cannot perform CA on TP for moderate complexity testing unless they can qualify as a TC. Therefore, if a laboratory performs both moderate and high complexity testing, a GS can only perform CA on moderate complexity TP if they can meet the regulatory requirements of a TC. The proposed change would allow individuals with applicable associate degrees to assess competency in laboratories that perform both moderate and high complexity testing and bring parity to who performs CA for all nonwaived laboratories while maintaining the laboratory's ability to produce accurate and reliable testing.

At § 493.1411(b), we proposed adding a requirement at paragraph (b)(6) to allow individuals who are qualified under § 493.1411(b)(1), (2), (3), or (4) or have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution and have at least 2 years of laboratory training or experience, or both, in blood gas analysis to qualify as TC for blood gas testing only. Most blood gas testing was categorized as high complexity when the original regulations were finalized in the February 1992 final rule with comment period. Due to improved technology, most routine blood gas testing is now categorized as moderate complexity. We proposed this change because we believe that it would provide adequate oversight of moderate complexity blood gas testing. Adding this provision specific to TCs in the area of blood gas testing would allow individuals to qualify as a TC in this specific area of expertise. Please note that we will still not consider a degree in respiratory therapy (RT) or cardiovascular technology to be equivalent to a biological or chemical science degree. However, an individual with a degree in either respiratory or cardiovascular therapy would be able to oversee the testing and CA of only those personnel who perform blood gas testing.

At § 493.1411(b)(7), we proposed adding a grandfather provision to include those already qualified prior to the date of the final rule, including nurses.

We received public comments on these proposals at § 493.1411. The following is a summary of the public comments we received and our responses.

Comment: Several commenters supported the proposed TC qualification route for an associate degree in medical laboratory technology or clinical laboratory science and at least 4 years of laboratory training or experience, or both, in nonwaived testing and the designated specialty or subspecialty areas of service for which the TC is responsible for qualifying as TCs.

Response: We appreciate the commenters' support and are finalizing these proposed changes with modification, to include medical laboratory science in addition to medical laboratory technology and clinical laboratory science as degree paths, when applicable, as discussed in response to comments in section III.C.3. of this rule.

Comment: Several commenters supported the proposal to include a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution to the TC qualifications for blood gas analysis. Additional commenters requested clarification on the proposed requirement for 2 years of laboratory training and experience for TCs that earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution. The commenter inquired if the 18 months of clinical experience acquired during respiratory therapy school would count towards the required 2 years. The commenter stated that requiring an additional 6 months of training and education may limit hiring respiratory therapists (RT) directly from programs. The commenter added that if clinical rotations during RT school do not count toward the required 2 years of laboratory training and experience, then all newly graduated RTs would be prevented from performing blood gas analysis which is an essential function in the hospital setting. Another commenter suggested that instead of requiring 2 years of laboratory training and experience, RTs must be graduates of professionally accredited respiratory therapy or pulmonary technology programs. The commenter added that RTs are sufficiently trained and proficient in arterial puncture, blood gas collection, analysis, and interpretation, ensuring the quality and accuracy of collected samples. These commenters agreed

that blood gas analysis is an integral part of emergency and critical patient care decision-making that requires immediate collection, analysis, and results reporting, and stated that the proposed changes will prevent newly graduated RTs from obtaining the necessary experience and will impose further strains on hospitals to find qualified personnel when there is already a severe shortage nationwide.

Response: The current and proposed TC qualifications for a bachelor's degree also require at least 2 years of laboratory training or experience or both in nonwaived testing in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. The proposed TC qualifications for blood gas analysis parallel these requirements by including the two-year requirement of laboratory training or experience in blood gas analysis for a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution. We believe it is important for a TC in blood gas analysis to have at least 2 years of laboratory training or experience to be consistent with the qualification requirements for general TCs. The 18 months of clinical rotations acquired during respiratory therapy or pulmonary technology school may count towards the requirement for 2 years of laboratory training and experience.

In this final rule, consistent with our proposed and final policy, we are also reformatting proposed § 493.1411(b)(3) and (4) to clarify that individuals qualifying with a traditional doctoral, master's or bachelor's degrees and those qualifying under the new educational pathway must all have the required years of laboratory training or experience. As we discussed in the proposed rule, all individuals qualifying through an educational pathway must also meet training and/or experience requirements.

We are also updating the regulatory cross-reference at finalized § 493.1411(b)(3)(i)(B) and (b)(4)(i)(B) for consistency with the reformatting of the final regulations in this section.

After consideration of public comments, we are finalizing the proposed changes to §493.1411(b), with the following modifications:

- To add medical laboratory science where applicable in this section.
- To reformat the regulations at § 493.1411(b)(3) and (4).
- To update the regulatory cross-references at § 493.1411(b)(3)(i)(B) to "§ 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (b)(4)(i)(C)".
- To update the regulatory cross-reference at §493.1411(b)(4)(i)(B) to § 493.1405(b)(5)(i)(B).

7. Testing personnel qualifications (§ 493.1423)

We proposed redesignating § 493.1423(b)(2), (3), and (4) as § 493.1423(b)(4), (5), (6), respectively.

We also proposed separating current paragraph (b)(1) into two separate provisions. Revised paragraph (b)(1) would include the current requirement of a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located. New paragraph (b)(2) would include the requirement of an earned doctoral, master's, or bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution. As discussed in section III.B.17. of the proposed rule, we proposed removing an earned doctoral, master's, or bachelor's degree in "physical science" as a means to qualify. In addition, we proposed adding an earned doctoral, master's, or bachelor's degree in nursing as a means to qualify. In Survey and Certification memo 16-18-CLIA,[22] we stated that "a bachelor's in nursing meets the requirement of having earned a bachelor's degree in a biological science for high complexity TP" and that "an associate degree in nursing meets the requirement of having earned an associate degree in a biological science for moderate complexity TP." We stated in the proposed rule that we appreciate all comments received in response to the 2018 RFI and agree that a nursing degree is not equivalent to a biological or chemical science degree. We further stated that we also concur with some

[22] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-16-18.html?DLPage=1&DLEntries=10&DLFilter=16-18&DLSort=3&DLSortDir=descending.*

commenters' recommendation that nursing degrees be used as a separate qualifying degree for TP. As testing practices and technologies have evolved, point of care testing has become a standard of practice in many health care systems, allowing laboratory results to be delivered to the treating health care provider as rapidly as possible. We recognize that in many health care systems, nurses perform the majority of the point of care testing in many different scenarios (for example, bedside, surgery centers, end-stage renal disease facilities). We stated that we do not have any reason to believe that nurses would be unable to accurately and reliably perform moderate and high complexity testing with appropriate training and demonstration of competency.

We proposed adding new paragraph (b)(3) to include the requirement that the individual must meet the criteria in § 493.1405(b)(3)(ii), (b)(4)(ii), (b)(4)(iii) or (b)(5)(ii) (finalized in this final rule at § 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C), and (b)(5)(i)(B)) to allow individuals who do not have a chemical, biological, or clinical laboratory science or medical technology degree to be eligible to qualify as a TP using the educational algorithm. See discussion in section III.B.3. of the proposed rule.

In addition, we proposed adding at paragraph (b)(7) a requirement to allow individuals who perform blood gas testing to be qualified under § 493.1423(b)(1) through (4) or have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution or have an associate degree related to pulmonary function and have at least 2 years training or experience or both in blood gas analysis. We proposed this addition so that parity can exist with high complexity TP requirements for blood gas testing at § 493.1489(b)(6). See previous discussion at § 493.1411(b).

We received public comments on these proposals at § 493.1423. The following is a summary of the public comments we received and our responses.

Comment: Many commenters opposed the proposed addition of a nursing degree to qualify as testing personnel in laboratories that are performing moderate complexity testing.

Many commenters noted that the proposed rule stated that responses to the RFI did not concur that nursing degrees were equivalent to biological or chemical sciences degrees, and the majority of the commenters on the proposed rule agreed, stating that there is very little laboratory science coursework in a nursing degree program. Commenters agree that nursing professionals are highly skilled and extremely valuable members of the healthcare workforce. However, commenters stated their education and training do not emphasize the skills needed to accurately perform moderate and high complexity testing, which, by their definition, have a higher degree of potentially negative impact on the patient if performed incorrectly. Commenters noted the specific laboratory science courses that laboratory technicians and medical laboratory scientists must complete in contrast to the single chemistry course required by many nursing degrees. Others added that nursing coursework does not provide the knowledge to understand and correctly perform moderate and high complexity testing, including the fundamental aspects of clinical laboratory testing such as QC, delta checks, specimen integrity, confounding variables, chemical interactors/inhibitors, and many other relevant topics required to carry out these higher levels of testing accurately. Many commenters agreed that POC testing is not equivalent to moderate or high complexity testing and stated that allowing anyone to work in a clinical laboratory without the proper training will put patients at risk. Many commenters provided examples of personal situations where an individual with a nursing degree was unable to accurately perform or understand clinical laboratory testing, including POC tests. Others commented that both nursing and laboratory fields are facing national workforce shortages, and nursing professionals are already overburdened with additional duties.

Response: We recognize that many interested parties do not consider a nursing degree equivalent to a chemical, biological, clinical or medical laboratory science, or medical technology degree. However, since 2016, CMS has considered nursing degrees equivalent to biology degrees. In Survey and Certification memo 16–18–CLIA, we stated that ‘‘a bachelor’s in nursing meets the requirement of having earned a bachelor’s degree in a biological science for

high complexity TP'' and that ''an associate degree in nursing meets the requirement of having earned an associate degree in a biological science for moderate complexity TP.'' As stated in the proposed rule, POC testing has become a standard of practice in many healthcare systems, allowing laboratory results to be delivered to the treating healthcare provider as rapidly as possible. We recognize that in many healthcare systems, nurses perform the majority of the POC testing in many different scenarios (for example, bedside, surgery centers, and end-stage renal disease facilities). Our experience since 2016 demonstrates that nurses with appropriate training and demonstration of competency are able to accurately and reliably perform moderate complexity testing. We also recognize that in response to the RFI, many interested parties suggested nursing degrees could be used as a separate qualifying degree for nonwaived testing personnel. We therefore proposed to incorporate a pathway for nursing degree candidates to qualify as testing personnel in laboratories performing moderate complexity testing. As with all testing personnel, the laboratory director is responsible for ensuring that before testing patient specimens, all personnel have the appropriate training, and can demonstrate that they can perform all testing operations reliably to provide and report accurate results. Under this final rule, individuals with nursing degrees will only be able to qualify for personnel positions listed in subpart M when a nursing degree is specifically listed in the regulatory qualifications. For example, revised § 493.1423 includes nursing degrees for moderate complexity testing personnel. However, individuals with nursing degrees will no longer be able to qualify as LDs as nursing is not listed as a qualifying degree under revised § 493.1405(b).

We note that as discussed in the proposed rule, our intent is to allow individuals already qualified and employed in a given personnel capacity as of the date of the final rule to continue to be qualified under the new provisions (that is, grandfathered), provided they are continuously employed in their position after the effective date. We proposed grandfathering provisions at §§ 493.1405(b)(6), 493.1411(b)(7), 493.1443(b)(4), 493.1461(c)(4), 493.1483(b)(3), and 493.1489(b)(5), but inadvertently omitted the applicable grandfather provisions in §§ 493.1423

and 493.1449. We are including those provisions in this final rule at §§ 493.1423(b)(8) and 493.1449(j), respectively. Like the other new grandfather clauses, this one allows individuals already qualified and employed in the applicable personnel position as of the effective date of the final rule to continue to be qualified under the new provisions provided the individuals remain continuously employed in their position after the effective date.

Comment: A commenter suggested a definition for "blood gas testing" to indicate if it includes oxygen saturations and co-oximetry testing as well as to include or exclude venous and capillary gases since arterial samples are the most common sample type but not defined in the proposed change. The commenter stated that emergency medical technicians need to run blood gases during critical patient transport and may not qualify as testing personnel. The commenter stated that critical patients need hands-on life-saving support and that a trained, competent, and experienced high school diploma testing personnel should be allowed to run a blood gas test in a POC device.

Response: CLIA allows moderate complexity testing personnel to qualify with a high school diploma or equivalent and documented training of the testing performed prior to reporting patient test results. Individuals who meet the regulatory qualifications for moderate complexity can perform any test categorized by the FDA as moderate complexity, including blood gases. No change is necessary to the regulations.

Comment: As discussed in the comment section for the proposed changes to the technical consultant qualifications, several commenters requested clarification on the proposed requirement for 2 years of laboratory training and experience for RTs and inquired if the 18 months of clinical experience acquired during respiratory therapy school would count towards the required 2 years.

Response: The 18 months of clinical rotations acquired during respiratory therapy or pulmonary technology school may count towards the proposed requirement for 2 years of laboratory training and experience.

In this final rule, we are also adding "laboratory" where training is required at proposed § 493.1423(b)(6)(ii) and (b)(7)(iii)(B) to clarify the type of acceptable training, consistent with the new definition of "laboratory training or experience" at 42 CFR 493.2 and related discussion in the July 2022 proposed rule at 87 FR 44911-44913 that training and experience must be in a CLIA laboratory (87 FR 44911-44913). We are reformatting § 493.1423(b)(7) to clarify that there are three distinct pathways to qualify as testing personnel for blood gas analysis under this subsection as discussed in the July 2022 proposed rule (87 FR 44919-44920). We are correcting and updating cross-references in the regulatory text where necessary for consistency with the reformatting of the final regulations.

As previously discussed, we are adding the grandfathering clause in this final rule at § 493.1423(b)(8). Like the other new grandfather clauses, this one allows individuals already qualified and employed as moderate complexity testing personnel as of the effective date of the final rule to continue to be qualified under the new provisions provided the individuals remain continuously employed in their position after the effective date.

We are also making technical changes in this section of the final regulations to enhance consistency.

After consideration of the comments received, we are finalizing the proposed provisions at § 493.1423, with the following modifications:

- To include medical laboratory science where applicable, as discussed previously in this section.
- To reformat the regulations at § 493.1423(b)(7).
- To update the regulatory cross-references at § 493.1423(b)(3).
- To add "laboratory" where training is required as reflected at § 493.1423(b)(6)(ii) and (b)(7)(iii)(B).
- To add the grandfathering clause in the final regulatory text at § 493.1423(b)(8).

8. Laboratory director qualifications (§ 493.1443)

As discussed in section III.B.3. of the proposed rule, we proposed to amend § 493.1443(b)(1)(ii) by removing "or possess qualifications that are equivalent to those required for such certification." Also, as discussed in section III.B.3. of the proposed rule, we proposed to amend § 493.1443(b)(2) by removing the residency requirement at paragraph (b)(2)(i) as a means to qualify and redesignating at paragraph (b)(2)(ii) (which requires the individual to have at least 2 years of experience directing or supervising high complexity testing). In addition, we proposed adding a new paragraph (b)(2)(ii), to require 20 CE credit hours. (As discussed later in this section of the final rule, these provisions in the proposed rule at (b)(2) are being reformatted and finalized at the revised (b)(2)(i) through (iii)).

We proposed redesignating current paragraph (b)(3)(i) as new paragraph (b)(3)(iii) and redesignating the provisions of paragraphs (b)(2)(ii)(A) and (B) as new paragraphs (b)(3)(iv). (As discussed later in this section of the final rule, these provisions in the proposed rule at (b)(3) are being reformatted and finalized at the revised (b)(3)(i) through (iv)).

As discussed in section III.B.17 of the proposed rule, we proposed redesignating the introductory text of paragraph (b)(3) as new paragraph (b)(3)(i) to revise this paragraph by removing an earned doctoral, master's, or bachelor's degree in "physical science" as a means to qualify. As discussed in section III.B.8. of the proposed rule, we would revise newly redesignated paragraph (b)(3)(i) by adding an earned doctoral degree in "medical technology" as a means to qualify. (As discussed later in this section of the final rule, this provision in the proposed rule at (b)(3)(i) is being reformatted and finalized at (b)(3)(i)(A)).

As discussed in section III.B.8 of the proposed rule, we proposed adding an educational requirement at new paragraph § 493.1443(b)(3)(ii) that includes a qualification algorithm for an individual that does not have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology. As discussed in this section of the final rule, this provision in the proposed rule at (b)(3)(ii) is being reformatted and finalized at (b)(3)(i)(B).

At paragraphs § 493.1443(b)(3)(ii) and (b)(4) and (5), we proposed deleting these paragraphs to remove the grandfather provisions as these requirements had to have been met by February 24, 2003, March 14, 1990, and February 28, 1992, respectively, and individuals can no longer qualify under these provisions. We proposed adding a new paragraph (b)(4) to specify the new grandfather provision. We also proposed redesignating paragraph (b)(6) as new paragraph (b)(5).

Finally, as discussed in section III.B.3. of the proposed rule, we proposed adding a 20 CE credit hour requirement at new paragraph § 493.1443(b)(3)(v). As discussed in this section of the final rule, this provision in the proposed rule at (b)(3)(v) is being reformatted and finalized at (b)(3)(iv).

We received public comments on these proposals at § 493.1443. The following is a summary of the public comments we received and our responses.

Comment: Many commenters opposed the proposed addition of an educational requirement that includes a qualification algorithm for an individual with a master's degree equivalency that does not have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology to qualify as a high complexity laboratory director (HCLD). Commenters stated that doctoral-level HCLDs are critical in ensuring high-quality, appropriate patient care. HCLDs are responsible for overseeing all clinical and scientific aspects and related operational aspects of the laboratory. Their responsibilities include introducing, developing, validating, implementing, and interpreting laboratory tests. Commenters added that any pathway to high complexity laboratory directorship, such as the proposed master's degree equivalence that bypasses PhD-level training, could jeopardize patient care and does not acknowledge the importance of scientific and medical expertise essential to becoming a qualified HCLD. Another commenter stated that the limited exposure that a master's degree candidate receives is insufficient to serve as an HCLD noting that running a high complexity laboratory requires critical thinking and subject matter expertise. Several commenters stated that the

master's degree does not provide the rigorous research component required by most doctoral programs. They indicated that research is critical to developing and refining the techniques and skills that are needed by the HCLD to serve their patients. They stated that this research component allows the person to think independently, identify and troubleshoot analytical problems that can affect the clinical interpretation, and provides them the competencies to develop and validate new tests, and much more. Another commenter noted that HCLDs' key responsibilities include analytical method selection for either replacing an outdated methodology or introducing a new one; communication with peer clinical colleagues and effective responses to queries on individual laboratory test results; producing and updating as needed, patient-focused reporting of results that make use of established reference ranges for distinguishing between normal and abnormal results; participation in regional, national or international discussion panels to review testing issues such as QC best practices, selection of best performing analytical methods; and presentation of studies that evaluate the overall clinical performance of tests and their robustness in practice. The commenter stated that master's degree program requirements do not meet the CLIA qualifications for a HCLD. The commenters opposed the proposed lowering of the HCLD qualifications to include a master's equivalency pathway. Some commenters stated that a doctoral-level or medical doctor degree should be the minimum educational qualification for a HCLD, given the importance of the role of overseeing the overall management of high complexity testing and laboratory operations of the clinical laboratory.

Response: We agree with the commenters that a medical or doctoral degree should be required as the minimum educational qualifications for a LD in laboratories performing high complexity testing. Therefore, we are revising § 493.1443(b)(3) as proposed to specify that the individual must have an earned doctoral degree for purposes of the doctoral degree algorithm. The current CLIA LD qualifications for laboratories performing high complexity testing (§ 493.1443) provide a pathway for individuals with a doctor of medicine, doctor of osteopathy,

doctor of podiatric medicine, or an earned doctoral degree. We agree that this will remain unchanged under the final rule.

Comment: Several commenters opposed the proposed inclusion of the DCLS as a doctoral degree qualification for HCLDs. Commenters stated several reasons for their opposition, including what they stated was the lack of a rigorous research component similar to what doctoral programs require. One commenter noted that most HCLDs have additional post-doctorate fellowship experience with rigorous clinical and operational training research specifically focused on their dedicated specialty. They stated that this research training is critical to developing and refining the techniques and skills an HCLD needs to serve their patients, including identifying and addressing problems affecting clinical interpretation and developing and validating new tests. Commenters also stated that individuals holding a PhD have post-doctoral experience in laboratory medicine, are board-certified and are professionally qualified as an HCLD. Commenters indicated that the DCLS degree is focused primarily on laboratory management with little concentration on laboratory testing or processes. One commenter was not aware of any organization that certifies the DCLS candidates as competent in laboratory medicine. Commenters also noted that an HCLD must have a wide range of knowledge in both analytical and clinical laboratory medicine and be able to teach pathology residents. In addition to the scientific responsibilities, the administrative duties require the HCLD to prepare an annual report for the laboratory, comply with all the Federal and State requirements, negotiate with the hospital administration a budget, justify new equipment, and hire and keep the laboratory staff. Commenters believed that individuals with a DCLS do not possess the scientific skills to design and interpret analytical assays, interpret unusual laboratory test results, check for interferences in laboratory tests, validate and troubleshoot an assay, decide which instrument, what automation system and what software programs should be used in the laboratory, and discuss key laboratory and clinical issues with clinicians in all fields of medicine. Another commenter stated that DCLS candidates are not required to pass a comprehensive exam before they can complete their

research and earn the degree, nor work as a teaching assistant to gain skills needed to give didactic lessons to a class and give presentations at conferences routinely allowing PhD candidates to become competent in addressing issues unique to the high complexity specialties that are not included in DCLS programs. Another commenter was concerned that there might be confusion among the public about the distinctions between a clinical pathologist (MD or DO) and a DCLS, emphasizing that pathologists (MD or DO) are licensed physicians who are trained in pathology to make medical diagnoses and that by their clinical training, including medical school and graduate medical education, and specialty certification in the medical disciplines of anatomic and clinical pathology, pathologists are uniquely best qualified to perform HCLD responsibilities. Commenters added that individuals with DCLS degrees need a more scientific and clinical background to participate in patient care. The commenters believed that finalizing the proposed DCLS qualification for HCLDs will increase the potential for patient harm.

In contrast, we also received many comments in support of the proposed recognition of the DCLS as a recognized doctoral degree to qualify as an HCLD. As noted by many commenters, the DCLS is the only doctorate whose primary specific focus is clinical laboratory testing. These commenters stated that it is the only degree based on uniform clinical laboratory testing accreditation standards with National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) accreditation. Commenters noted that currently, there are three DCLS programs in the U.S., and each requires laboratory experience (at least 3 years) before admission to the doctoral program. The commenters stated that the ASCP Board of Certification has committed to offering certification for the DCLS and that multiple DCLS graduates have already been board-certified as HCLDs by other HHS-approved certification boards, such as the National Registry of Certified Chemists (NRCC). Many commenters expressed that statements received from several laboratory professional organizations opposing the proposal to include DCLS as HCLD were not based on facts about the DCLS programs. Commenters added that as indicated in the American Society for Clinical Laboratory Science (ASCLS) DCLS Body of Knowledge

(BOK), an individual with a DCLS increases diagnostic efficiency, facilitates patient management outcomes, and improves timely access to accurate and appropriate laboratory information by participating directly in patient care decisions, monitoring laboratory utilization, and conducting research on the diagnostic process. The commenters stated that the BOK also outlines professional practice activities related to the five core competencies and the foundational knowledge required for professional practice. A commenter stated that no evidence had been provided that the DCLS is substandard or would be less qualified than current eligible doctorates in this role. The commenter stated that the argument that a PhD-like dissertation is not required of the DCLS is irrelevant since most professional doctorates opt instead for the more important extensive capstone laboratory science experience, culminating in a rigorous scholarly investigation on a relevant topic defended before a doctoral committee. Completing components in the advanced education of laboratory sciences, research, and residency is required for DCLS graduation. A commenter stated that completing the research component of DCLS training results in graduates who can translate research and evidence into best practices and design their research projects to improve patient care goals. DCLS graduates are required to complete institutional review board-approved research for the fulfillment of their degree. The DCLS is typically trained in more than one clinical laboratory area (for example, microbiology, chemistry, hematology, etc.), which helps understand the interrelatedness of laboratory test results. According to the commenters, the DCLS curriculum includes diagnostics, assay development, test interpretation, treatment, problem-solving, quality control, and statistical analysis, all critical elements of HCLD roles. Commenters further stated that contrary to some of the opposition expressed, the DCLS has significant experience in a clinical laboratory, and whether it is considered an advanced practice or entry-level degree makes little difference if the qualifications, competencies, and experiences are in place. Another supporting commenter added that the proposed inclusion of DCLS as HCLD will positively impact workforce shortages by establishing legal legitimacy for advanced practice and improving recruitment and retention of

skilled laboratorians to the workforce. Several commenters noted direct experience mentoring or working alongside DCLS graduates during their clinical residency and noted that DCLS graduates provided expert analysis of enterprise-wide laboratory test utilization, proposed interventions to change clinical and operational practices to optimize test use, contributed to multidisciplinary decision-making in test stewardship and other laboratory quality initiatives, provided consultation for optimizing information management, and provided direct laboratory test consultation to healthcare providers in surgical and medical intensive care units. Multiple commenters added that the DCLS practitioner is uniquely qualified to serve in multiple roles, including that of HCLD, because of their broad and advanced knowledge and training across all disciplines of the clinical laboratory (for example, hematology, hemostasis, immunohematology, clinical chemistry, microbiology) as opposed to the limited scope of one clinical discipline in some PhD training programs. Another commenter added that the DCLS's knowledge also provides for developing clinical and reflex test pathways and consultation services that provide knowledge to physicians for better patient management and test ordering as well as for decreasing costs. One commenter noted published article(s) demonstrated laboratory workforce shortages, professional burnout, and low salary and job satisfaction rates and suggested a leadership pathway such as the DCLS could help address these workforce challenges. Another commenter added that including the DCLS as HCLDs is the logical step for career growth for laboratorians. The commenter stated that the technical and scientific expertise of the highly driven laboratory scientist is often lost to nursing programs, physician assistant programs, medical schools, managerial roles relating to business goals, and industry positions. One commenter noted the potential benefits of allowing DCLS holders to serve as HCLDs, particularly in rural/small hospitals and reference laboratories that may not be able to afford an on-site pathologist or whose volume does not warrant the need for an on-site pathologist. The commenter stated that such underserved laboratories/facilities stand to gain by being allowed to hire DCLS graduates as HCLDs, who can serve not only in the capacity of CLIA director but

also oversee the day-to-day administrative/supervisory functions. Commenters agreed that with a strong background in clinical science, research, quality management, and cross-functional collaboration, the DCLS professional can positively impact the quality of patient care provided while improving healthcare efficiency. According to these commenters, the DCLS fills a much-needed gap in our healthcare system and will dramatically enhance and promote quality patient care while being a valuable healthcare team member.

Response: The current HCLD qualifications under § 493.1443(b)(3) states that the LD must hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution. In this final rule, we define "doctoral degree" to clarify what we mean by the term and to include the DCLS as an acceptable doctoral degree. Our experience under the prior regulations demonstrates that board-certified DCLS graduates are prepared to serve as HCLDs. As stated in the proposed rule, we agree that individuals with a DCLS are experts in clinical laboratory testing. We consider a DCLS an acceptable doctoral degree.

Comment: A commenter suggested that HCLDs should also be certified at a doctoral level in the applicable subdisciplines through the appropriate board (that is, American Board of Medical Microbiology) or in addition to physician (MD or DO) certification in anatomic or clinical pathology.

Response: HCLDs must be qualified to manage and direct laboratory personnel and performance of high complexity testing. HCLDs qualifying as MDs or DOs must be certified in anatomic or clinical pathology, or both, or have appropriate experience directing or supervising high complexity testing. The current and proposed qualifications for an HCLD with a doctoral degree include certification by a board approved by HHS. Both pathways require only one board certification. For example, if a HCLD is certified by the American Board of Pathology, we do not require additional certification in a subspecialty.

Comment: A commenter suggested that in addition to an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution, there should be a requirement for a completed doctoral dissertation in subjects related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings. The commenter stated that such a requirement would ensure that individuals who serve as LDs in laboratories performing high complexity testing have in-person, practical hands-on laboratory training and experience managing complex clinical testing and operations, ultimately ensuring high-quality patient care and safety.

Response: The current and proposed qualifications for an HCLD with a doctoral degree include certification by a board approved by HHS. Board certification and the doctoral degree together ensure the technical competence of medical laboratory professionals.

Comment: A commenter suggested that the grandfather clause(s) be retained in the final rule as that information is useful when determining if an individual qualifies under those routes.

Response: We proposed to remove the current grandfather clauses and add a new clause to indicate that an individual is considered qualified as a LD of high complexity testing under this section if they were qualified and serving as a LD of high complexity testing in a CLIA-certified laboratory as of the effective date of this final rule and have done so continuously since the effective date of this final rule. Also, we added this clause to other applicable sections, as proposed. Prior versions of the CFR are available free online at *https://www.govinfo.gov/app/collection/cfr.*

Comment: A commenter noted that the language in the proposed grandfather clauses indicated that they qualify only if they serve continuously in their position after the final rule's effective date. The commenter stated that this defeats CMS's stated intent to increase the number of eligible candidates needed to perform laboratory testing and is grossly unfair to individuals who qualify under a grandfathering provision and then suffer a break in service of even one day (for example, due to illness, family emergency, or sale of their laboratory) after the final rule is

published. The commenter requested a revision to allow breaks in service (for example, 3 years) before an individual had to requalify.

Response: The new provision will allow individuals qualified for specific personnel roles to continue serving in those roles as long as they have continued to perform those duties. The updates to the CLIA personnel requirements in this final rule provide additional pathways for individuals to qualify as personnel for both moderate and high complexity testing. Clarification regarding continuous service will be added to updated guidance.

In this final rule, we are also reformatting proposed § 493.1443(b)(2) to enhance consistency. Consistent with our proposed and final policy, we are also reformatting proposed § 493.1443(b)(3) to clarify that both individuals qualifying with traditional doctoral degrees and those qualifying under the new educational pathway must have the specified 20 CE credit hours, certification, and experience. As we explained in the July 2022 proposed rule (87 FR 44910-44911, 44920), 20 CE credit hours are required to qualify as an LD and individuals qualifying through an educational pathway must also have the required training or experience. In addition, as in the existing § 493.1443(b)(3), individuals qualifying through this subsection must also have the required certification.

We are making technical changes in this section of the regulatory text to enhance consistency.

We are also adding "approved" to the final regulatory text at § 493.1443(b)(3)(i)(B)(*2*) to clarify that if individuals are qualifying based on a thesis or research project, that thesis or research project must be approved, meaning the individuals must have received credit for it as reflected on their transcript. CMS's policy is to verify educational qualifications by reviewing transcripts, as described in its Survey and Certification Memorandum 16-18-CLIA*, Personnel Policies for Individuals Directing or Performing Non-waived Tests* at 2-4 (April 1, 2016), available at *https://www.cms.gov/medicare/provider-enrollment-and-*

certification/surveycertificationgeninfo/policy-and-memos-to-states-and-regions-items/survey-and-cert-letter-16-18.

After consideration of the comments received, we are finalizing the proposed changes to § 493.1443(b) with the following modifications:

- To include medical laboratory science as discussed previously in sections III.B.1. (§ 493.2) and III.B.3 (§ 493.1405) and to clarify the doctoral degree algorithm by specifying that an individual must hold an earned doctoral degree.
- To reformat § 493.1443(b)(2) and (3).
- To add "approved" as reflected at § 493.1443(b)(3)(i)(B)(*2*).

9. Laboratory director responsibilities (§ 493.1445)

For proposals related to § 493.1445, please see the discussion in this final rule at sections III.B.5: Laboratory director responsibilities for Laboratories Performing Moderate Complexity Testing (§ 493.1407).

We summarized the public comments related to on-site visits for purposes of both proposed revised § 493.1407 and proposed revised § 493.1445 in this final rule at section III.B.5: Laboratory Director Responsibilities for Laboratories Performing Moderate Complexity Testing (§ 493.1407).

After consideration of the comments received, we are finalizing the proposed changes to § 493.1445(c). In this final rule, we are also correcting and updating the regulatory cross-reference in the current regulations at § 493.1445(e)(10) from § 493.1489(b)(4) to § 493.1489(b)(5) for consistency with the finalized regulations.

10. Technical supervisor qualifications (§ 493.1449)

At § 493.1449, we proposed combining the provisions of paragraphs (c) through (g) into new paragraph (c) and combining paragraphs (h) through (j), (n), and (q) into a new paragraph (d). We also proposed redesignating paragraphs (k), (l), (m), (o), and (p) as paragraphs (e), (f), (g), (h), and (i), respectively. We proposed these changes to simplify the regulations by reducing

confusion and grouping identical TS requirements into a combined provision. We also proposed to insert the education algorithm at paragraph (c)(4)(i)(B).

At newly redesignated paragraph (e)(1)(ii), we proposed to remove the language at existing paragraph (k)(1)(ii)(B) since the American Society of Cytology has not provided certification for cytology since 1998; certification is provided by American Board of Pathology and American Board of Osteopathic Pathology.

At newly redesignated paragraph (d) (formerly paragraph (q)), we proposed amending the immunohematology requirement for the TS requirement to align with other TS qualifications and allow individuals with doctoral, master's, and bachelor's degrees with appropriate training and experience to qualify as a TS for immunohematology. This provision will be included in § 493.1449(d). The current regulation requires that the TS for immunohematology be a doctor of medicine or osteopathy. Fulfilling the CA requirements (for example, direct observation) can be challenging in rural facilities as the TS may not be onsite as the individual(s) may cover a large geographic area. Often a MT/CLS with a SBB (Specialist in Blood Bank) from ASCP (The American Society for Clinical Pathology)[23] is on-site to oversee the day-to-day operations of the blood bank. By allowing qualified individuals with doctoral, master's, or bachelor's degrees, to qualify as TSs, the personnel responsibilities will align with the current practices in laboratories without affecting the ability of the laboratory to provide accurate and reliable results. Further, the proposed change may help alleviate a shortage of physicians in rural areas and does not constitute a risk to public health or the individuals served by the laboratory.

As discussed in section III. B.16. of the proposed rule, we proposed at § 493.1449 to remove an earned doctoral, master's, or bachelor's degree in "physical science" as a means to qualify.

---

[23] *https://www.ascp.org/content/docs/default-source/boc-pdfs/exam-content-outlines/ascp-boc-us-procedures-book-web.pdf.*

We received public comments on these proposals at § 493.1449. The following is a summary of the public comments we received and our responses.

Comment: One commenter opposed the proposal to include qualification pathways for master's and bachelor's degree candidates to qualify as TSs in laboratories that perform testing in the specialty of immunohematology. The commenter stated that the immunohematology field is evolving into emerging uses such as hazards of therapies (for example, cellular therapy) in transfusion medicine, which require the expertise of a physician to oversee. Another commenter stated that the high risk associated with a mistake in immunohematology could cost a patient their life. Another commenter suggested removing a master's or a bachelor's degree as an equivalency to individuals with an MD, DO, Doctor of Podiatric Medicine (DPM), or an earned PhD in chemical, biological, or clinical laboratory science or medical technology in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology as delineated in paragraph (c)(4), and the subspecialty of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology, as delineated in paragraph (d)(4). The commenter stated that the breadth and depth of experience, training, critical thinking, and analytical skillset acquired from a master's or bachelor's degree, are considerably lower and notably less stringent than those obtained from a traditional doctoral degree and maintaining the current CLIA qualifications related to MD, DO, DPM, and doctoral degree would be consistent with the requirements for certification by all nine HHS-approved certification boards.

Response: The current CLIA regulations provide qualification pathways for master's and bachelor's degrees for the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, and virology and the specialties of diagnostic immunology, chemistry, hematology, and radiobioassay. We proposed to amend the immunohematology requirement to align with other TS qualifications and allow individuals with doctoral, master's, and bachelor's degrees with appropriate training and experience to qualify as a TS for immunohematology. As noted in the proposed rule, fulfilling the CA requirements (for example, direct observation) can be

challenging in rural facilities. A physician or doctoral-level TS may not be onsite as the individual(s) may cover a large geographic area. Allowing qualified individuals with doctoral, master's, or bachelor's degrees to qualify as TSs will align with the current practices in laboratories without affecting the ability of the laboratory to provide accurate and reliable results.

In this final rule, consistent with our proposed and final policy, we are also reformatting proposed § 493.1449(c)(3), (4), and (5) and § 493.1449(d)(3), (4), and (5) to clarify that individuals qualifying with a traditional doctoral, master's or bachelor's degree and those qualifying under the new educational pathway must all have the required years of laboratory training or experience. As we explained in the July 2022 proposed rule (87 FR 44911), the requirement for laboratory training and/or experience applies to all individuals qualifying through an educational pathway. We are also reformatting proposed §493.1449(h) to clarify that there are two pathways to qualify under this subsection. Those pathways were designated (h)(1) and (h)(1)(i) in the proposed regulation text and are being finalized as (h)(1) and (2).

We are making technical changes in the finalized regulatory text to enhance consistency. Specialty/subspecialty headers were also added to the regulatory text to identify each of the specialty/subspecialty sections. CMS is also correcting and updating cross-references in the finalized regulatory text where necessary for consistency with the reformatting of the finalized regulations or to correct technical errors.

In this final rule, at § 493.1449(c)(4)(i)(C)(*2*) we are revising to clarify that, under this educational pathway, 16 semester hours in a combination of graduate level coursework in the specified subjects and a thesis or research project related to CLIA laboratory testing is required and that, if an individual is qualifying based on a thesis or research project, that thesis or research project must be approved, meaning the individual must have received credit for it as reflected on their transcript. CMS's policy is to verify educational qualifications by reviewing transcripts, as described in its Survey and Certification Memorandum 16-18-CLIA*, Personnel Policies for Individuals Directing or Performing Non-waived Tests* at 2-4 (April 1, 2016), available at

https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-to-states-and-regions-items/survey-and-cert-letter-16-18.

We are adding "laboratory" where training is required at § 493.1449(i)(1) and (i)(2) in this final rule to clarify the type of acceptable training, consistent with the new definition of "laboratory training or experience" at 42 CFR 493.2 and related discussion in the July 2022 proposed rule that training and experience must be in a CLIA laboratory (87 FR 44911-44913).

As previously discussed in section III.B.7 of this final rule, we are also adding the grandfathering clause in the final regulatory text at § 493.1449(j). Like the other new grandfather clauses, this one allows individuals already qualified and employed as high complexity technical supervisors as of the effective date of the final rule to continue to be qualified under the new provisions provided the individuals remain continuously employed in their position after the effective date.

After consideration of the comments received, we are finalizing the proposed changes at § 493.1449, with the following modifications:

- To include medical laboratory science as discussed previously in sections III.B.1. (§ 493.2) and III.B.3. (§ 493.1405) of this final rule.
- To revise the regulatory text at § 493.1449(c)(4)(i)(C)(*2*) as described previously.
- To reformat § 493.1449(c)(3), (4), and (5), (d)(3), (4), and (5), and (h).
- To revise the regulatory cross-reference at § 493.1449(c)(3)(i)(B) to § 493.1443(b)(3)(i)(B) for consistency with the reformatting of the final regulations.
- To revise the regulatory cross-reference at § 493.1449(d)(3)(i)(B) to § 493.1443(b)(3)(i)(B) for consistency with the reformatting of the final regulations.
- To revise the regulatory cross-reference at § 493.1449(d)(4)(i)(B) to § 493.1449(c)(4)(i)(B) and § 493.1449(c)(4)(i)(C) for consistency with the reformatting of these final regulations.

- To revise the regulatory cross-reference at § 493.1449(d)(5)(i)(B) to § 493.1449(c)(5)(i)(B) for consistency with the reformatting of the final regulations.

- To revise the regulatory cross-reference at § 493.1449(e)(2) to paragraph (e)(1) for consistency with the final regulations.

- To revise the regulatory cross-reference at § 493.1449(f)(1)(ii) to paragraph (f)(1)(i)(B) for consistency with the final regulations.

- To revise the regulatory cross-reference at § 493.1449(f)(2)(ii) to paragraph (f)(2)(i)(B) for consistency with the final regulations.

- To revise the regulatory cross-reference at § 493.1449(f)(3)(ii) to paragraph (f)(3)(i)(B) to include both certification pathways in § 493.1449(f)(3)(i)(B).

- To revise the regulatory cross-reference at § 493.1449(g)(3) to paragraph (g)(1) for consistency with the final regulations.

- To revise the regulatory cross-reference at § 493.1449(h)(2)(i) to § 493.1443(b)(3)(i)(B) for consistency with the reformatting of the final regulations.

- To add "laboratory" where training is required at § 493.1449(i)(1) and (2).

- To add "or" to the revised regulatory text at § 493.1449(i)(2)(i), clinical cytogenetics, to clarify the two pathways under this regulation.

- To add specialty/subspecialty headers in the regulations at § 493.1449(c) through (i) to identify each of the specialty/subspecialty sections.

- To update the regulatory cross-reference of "paragraph (h)" at § 493.1449 in the regulatory text "Note 1" to "paragraphs (b) through (i)" because Note 1 applies to paragraphs (b) through (i), not just (h).

- To add the grandfathering clause to the final regulatory text at § 493.1449(j).

11. General supervisor qualifications (§ 493.1461)

As discussed in section III.B.17. of the proposed rule, we proposed at § 493.1461(c)(1)(i) to remove an earned doctoral, master's, or bachelor's degree in "physical science" as a means to

qualify. At § 493.1461(c)(3) through (5), we proposed deleting the grandfather provisions as these requirements had to have been met by February 28, 1992, April 24, 1995, and September 1, 1992, respectively, and individuals can no longer qualify under these provisions. We stated that we plan to grandfather all individuals qualified under this provision. We also proposed adding new paragraph (c)(4) to specify a new grandfather provision for those individuals who had qualified prior to the publication of the final rule.

We received public comments on these proposals at § 493.1461. The following is a summary of the public comments we received and our responses.

Comment: A commenter stated that personnel qualifications do not recognize individuals with MLT or MT, and there is a need to ensure that individuals without associate degrees have pathways to qualify as a GS. The commenter noted the current CLIA exception allowing qualification by passing grade in a proficiency examination as indicated at 493.1461(c)(3)(ii).

Response: The current and proposed regulations for TP under § 493.1489 provide a pathway for individuals to qualify through education and training without possessing an earned associate degree. For example, if an individual is qualified as TP under § 493.1489(b)(3) as revised; and has at least 2 years of laboratory training or experience in high complexity testing, they will qualify as a GS.

In this final rule, we are also correcting and updating the regulatory cross-references in the current regulations at § 493.1461(e)(2) and (3) for consistency with the finalized regulations.

After consideration of the comments received, we are finalizing the proposed changes to § 493.1461(c) through (e), with the following modifications:

- To include medical laboratory science at § 493.1461(c)(1).
- To update the regulatory cross-reference at § 493.1461(e)(2) from "§ 493.1449(l) or (2)" to § 493.1449(f)(2).
- To update the regulatory cross-reference at § 493.1461(e)(3) from § 493.1449(l)(3) to § 493.1449(f)(3).

12. General supervisor qualifications on or before February 28, 1992 (§ 493.1462)

At § 493.1462, we proposed removing the grandfather provision as this requirement must have been met by February 28, 1992. We stated that these individuals would be included in the new grandfather provision at § 493.1461(c)(4).

We received public comments on these proposals at § 493.1461(c)(4). The following is a summary of the public comments we received and our responses.

Comment: A commenter was concerned that the proposed changes to GS would affect current GSs who qualified under the § 493.1462 grandfather clause.

Response: We plan to grandfather individuals qualified under § 493.1462 under the new provision § 493.1461(c)(4). We are finalizing a new paragraph (c)(4) that will consider an individual qualified as a GS if they were qualified and serving as a GS in a CLIA-certified laboratory as of the effective date of the final rule and have done so continuously since the effective date of the final rule.

After consideration of the comments received, we are finalizing the removal of § 493.1462.

13. General supervisor responsibilities (§ 493.1463)

At § 493.1463(b)(4), we proposed revising the language stating the need to annually evaluate and document the performance of all testing personnel to now require the evaluation and documentation of the competency of all testing personnel. Historically, CLIA has allowed the TS to delegate all CA to the GS. However, the current regulations only speak to the ability of the GS to perform annual CA. We clarified that the LD or TS may delegate both the semi-annual and the annual CA.

We received public comments on these proposals at § 493.1463. The following is a summary of the public comments we received and our responses.

Comment: A commenter requested that the responsibilities specified in § 493.1463(b)(4) be further clarified to articulate that GSs in a laboratory that performs both high and moderate

complexity testing are qualified to assess the competency of both high complexity TP and moderate complexity TP. The commenter stated that the term "all personnel" in the rule is ambiguous because the GS is a position included in the personnel for laboratories performing high complexity testing and can oversee CA for high complexity TP. The commenter noted that moderate complexity testing could also be performed in a high complexity laboratory with a GS, and the GS should be able to perform CA on TP performing moderate complexity testing.

Response: The proposal under § 493.1463(b)(4) pertains to all TP, including those performing moderate complexity tests. This allows GSs in laboratories that perform both moderate and high complexity testing to perform the CA on both moderate and high complexity testing personnel. The CMS SOM, Appendix C will be updated.

After consideration of the comments received, we are finalizing the proposed changes to § 493.1463 without modification.

14. Cytotechnologist qualifications (§ 493.1483)

At §§ 493.1483(b)(2) and 493.1489(b)(2)(ii)(B)(*1*), we proposed to replace "CAHEA" with CAAHEP (Commission on Accreditation of Allied Health Education Programs) and to remove, "or other organization approved by HHS." In October 1992, the American Medical Association (AMA) announced its intent to support the establishment of a new and independent agency to assume the accreditation responsibilities of the Commission on Allied Health Education Accreditation (CAHEA), which is CAAHEP. HHS has no approval process for programs not approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES) or CAAHEP.

At § 493.1483(b)(3) through (5), we proposed removing the grandfather provisions as these requirements had to have been met by September 1, 1992, or September 1, 1994, as individuals can no longer qualify under these provisions. We stated that we plan to grandfather all individuals qualified under this provision prior to the date of the final rule. These individuals would be included in the new grandfather provision at § 493.1483(b)(3).

We did not receive public comments on this provision, and are finalizing the proposed changes to § 493.1483. In this final rule, we are also correcting and updating the regulatory cross-reference in the introductory text of the current regulations at § 493.1483, from § 493.1449(k) to § 493.1449(e), for consistency with the finalized regulations.

15. Testing personnel qualifications (§ 493.1489)

We proposed removing paragraph (b)(3) as the February 28, 1992, grandfather provision must have been met by February 28, 1992. We also proposed redesignating paragraphs (b)(2)(i) and (ii) to paragraphs (b)(3)(i) and (ii), respectively. As noted, at § 493.1489(b)(3)(ii)(B)(*1*), we proposed replacing "CAHEA" with "CAAHEP" and removing "or other organization approved by HHS."

In addition, we proposed revising paragraph (b)(1) to separate the provisions into two paragraphs (that is, paragraph (b)(1) and new paragraph (b)(2)(i)). New paragraph (b)(1) would include the current requirement of a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located. New paragraph (b)(2)(i) would include an earned doctoral, master's, or bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution. As discussed in section III.B.17. of the proposed rule, we proposed removing an earned doctoral, master's, or bachelor's degree in "physical science" as a means to qualify. We proposed adding an earned doctoral, master's, or bachelor's degree in nursing as a means to qualify. In addition, we proposed adding new paragraph (b)(2)(ii) to state who may be qualified under § 493.1443(b)(3) or § 493.1449(c)(4) or (5) to allow individuals who do not have a chemical, biological, or clinical science or medical technology or clinical laboratory science degree to be eligible to qualify as a TC using the educational algorithm.

At § 493.1489(b)(4), we proposed amending this requirement by moving the military provision out of the April 24, 1995, grandfather provision and making it a mechanism that individuals will be able to qualify for moderate complexity testing (§ 493.1423(b)(3)). We

believe these individuals have the requisite educational background to meet the requirements to perform laboratory testing under CLIA. In addition, we proposed removing paragraph (b)(4) introductory text and paragraph (b)(4)(i) [the text that currently states "On or before" through "graduated from a [ML] or [CL] training program approved or accredited by ABHES, CAHEA, or other organizations approved by HHS"] per the discussion under § 493.1483(b)(2). As a result, the current military requirement at paragraph (b)(4)(ii) would be redesignated as paragraph (b)(4).

We received public comments on these proposals at § 493.1489. The following is a summary of the public comments we received and our responses.

Comment: Over 19,000 commenters provided a standardized "form letter" comment opposing the inclusion of nursing degrees (bachelor's and up) in the CLIA high complexity testing personnel requirements. In addition to the duplicate comments, we received many comments related to the inclusion of nursing degrees for high complexity testing personnel qualifications. The commenters stated that nursing degrees provide only a fraction of the academic science and little, if any, of the clinical training in non-waived laboratory testing that is required to qualify laboratory professionals. Bachelor's degrees in medical laboratory science, biology, and chemistry generally require at least 35-45 SH of academic science, with significant upper-level coursework. Commenters stated that in contrast, bachelor's degrees in nursing often require less than 14 SH in biology and/or chemistry, and usually only at the introductory level.

Response: After consideration of the public comments, we are not finalizing the proposed addition of a nursing degree in the revised § 493.1489(b)(2)(i) as a qualification for high complexity laboratory testing personnel. High complexity laboratory testing requires a higher level of knowledge; training and experience; troubleshooting and equipment maintenance skills; and interpretation and judgement than moderate complexity testing. Knowledge includes, but is not limited to, preanalytic, analytic and postanalytic phases of testing, calibration, quality control, and proficiency testing. We agree with the commenters that this knowledge and

experience may not be obtained in the nursing curriculum despite its science course requirements. We believe that individuals with biological or chemical science degrees, clinical laboratory science, medical technology, and medical laboratory science have a better knowledge base for high complexity testing. Nurses who have the appropriate science courses and training may still qualify under § 493.1489(b)(2)(ii) and will be evaluated on a case-by-case basis. When performing an analysis of all the comments received, several additional themes emerged, including the lack of laboratory training that nursing professionals acquire, the additional burden that nurses would incur by performing high complexity testing, the concern for patient safety, and the differences between POC testing (which is classified as waived or moderate complexity testing only) and high complexity testing. Beginning with the effective date of this final rule, individuals with nursing degrees will only be able to qualify for personnel positions listed in subpart M when a nursing degree is specifically listed in the regulatory qualifications. Nursing degrees will qualify under moderate complexity testing personnel. However, individuals with nursing degrees will no longer be able to qualify as high complexity testing personnel. All individuals, including those with nursing degrees, who are currently in positions listed in subpart M prior to the effective date of the final rule will be grandfathered as long as they meet the applicable grandfather provision, including the requirement for continuous employment in their position since the effective date of the final rule.

Comment: A commenter requested to revise § 493.1489 to add "or" at the end of paragraph (6)(i) to be consistent with similar proposed changes elsewhere in the proposed rule.

Response: We agree with the commenter and will amend § 493.1489(b)(6)(i).

In this final rule, we are also updating the regulatory cross-reference at § 493.1489(b)(7) for consistency with the finalized regulations.

After consideration of the comments received, we are finalizing the proposed changes to § 493.1489(b) with the following modifications:

- To include medical laboratory science at § 493.1489(b)(2)(i), consistent with similar changes as discussed elsewhere in this final rule, and to remove the proposed addition of a nursing degree at § 493.1489(b)(2)(i).
- To add "or" at the end of § 493.1489(b)(6)(i).
- To update the regulatory cross-reference at § 493.1489(b)(7) from § 493.1449(l) to § 493.1449(f) for consistency with the finalized regulations.

16. Technologist qualifications on or before February 28, 1992 (§ 493.1491)

We proposed removing § 493.1491 as individuals can no longer qualify under this provision.

We did not receive public comments on this provision and are finalizing the proposed change to remove § 493.1491. Individuals qualified under the previous § 493.1491(b)(6) are grandfathered by the new provision at § 493.1489(b)(5), provided they have been continuously employed in their positions since the effective date of this final rule.

17. Proposed removal of earned degree in physical science as an educational requirement

At §§ 493.1405, 493.1411, 493.1423, 493.1443, 493.1449, 493.1461, and 493.1489, we proposed to remove "physical science" and add a new educational requirement for the ability to qualify based on SH. We concur with CLIAC's recommendation that a degree in physical science should be removed from the CLIA regulations as it is too broad and may not include relevant laboratory science coursework. It is a broad discipline often described as the study of nonliving systems, such as astronomy, physics, and earth sciences. Generally, these types of degrees are not related to clinical laboratory testing. Due to variation in usage and the absence of universally accepted definitions, a "physical science degree" is difficult to define for regulatory purposes. We stated that we believe that the proposed semester algorithm will allow individuals to qualify in the absence of a traditional chemical, biological, or clinical laboratory science or medical technology degree. An individual graduating with a physical science degree may or may

not have sufficient course experience to meet the educational requirement, so the degree alone should not be listed among those that satisfy the educational requirement. We note that in some instances, individuals with these types of degrees have been able to qualify as high complexity TP under § 493.1489 and GSs under § 493.1461(b)(2) as long as they have the applicable training or experience (see section I.D.1.c. of the proposed rule).

We received public comments on these proposals. The following is a summary of the public comments we received and our responses.

Comment: Many commenters agreed with removing physical science as a qualifying degree, stating that it is not applicable to clinical laboratory work. A commenter noted that it takes years to become proficient in performing high complexity testing, such as identifying abnormal cells in blood, body fluids, and tissues, and disagreed with the removal of physical science as a qualifying degree.

Response: We agree that physical science coursework may not be applicable to clinical laboratory work, as discussed in the proposed rule. We also concur with CLIAC's recommendation that a degree in physical science should be removed from the CLIA regulations as it is too broad and may not include relevant laboratory science coursework. We have added an algorithm that may continue to allow individuals with physical science degrees to qualify provided they meet the requirements specified in the educational algorithm.

After consideration of the comments received, we are finalizing the proposed changes at §§ 493.1405, 493.1411, 493.1423, 493.1443, 493.1449, 493.1461, and 493.1489 to remove "physical science."

18. Clinical Laboratory Science and Medical Technology

At §§ 493.1405(b)(3) and (b)(5)(i), 493.1411(b)(4) and (6), 493.1443(b)(3)(i), and 493.1449(c)(3)(i), (c)(5)(i), (d)(3)(i), (d)(5)(i), (h)(2)(i), and (i)(2)(i), we proposed to remove any text referring to "medical technology" degrees and replace such text with references to degrees in "clinical laboratory science and medical technology" so that the latter phrase appears

consistently throughout subpart M. Originally, degrees were given in medical technology; however, the naming convention for medical technology degrees has changed since the regulations were first published in the February 1992 final rule with comment period. We stated in the proposed rule that the degree is now referred to as clinical laboratory science and that a clinical laboratory science degree is synonymous with a medical technology degree.

We received public comments on these proposals. The following is a summary of the public comments we received and our responses.

Comment: Several commenters suggested the inclusion of medical laboratory science in addition to clinical laboratory science and medical technology throughout the personnel qualifications.

Response: We agree with the commenters and are amending applicable sections of subpart M to include both clinical and medical laboratory science, as discussed previously.

After consideration of the comments received, we are finalizing the proposed changes as indicated in sections III.B.1, 3, 6, 7, 8, 10, and 11 of this final rule. We are also amending applicable sections of subpart M in this final rule to include medical laboratory science.

19. Other Conforming Amendments

In preparing this final rule, we identified regulatory cross-references in certain existing regulations that will be outdated as a result of our proposed and final changes to the subpart M regulations. Accordingly, in this final rule we are updating the regulatory cross-references at §§ 493.945(b)(2), (b)(3)(i), (b)(3)(ii)(C) and (F), 493.1273(b), 493.1274(c)(1), 493.1417(a), 493.1451(c), 493.1455(a), and 493.1469(a) to be consistent with the finalized regulations. Specifically, we are updating:

- the regulatory cross-reference at § 493.945(b)(2) from § 493.1449(k) to 493.1449(e).
- the regulatory cross-reference at § 493.945(b)(3)(i) from § 493.1449(k) to 493.1449(e).

- the regulatory cross-reference at § 493.945(b)(3)(ii)(C) from § 493.1449(k) to 493.1449(e).

- the regulatory cross-reference at § 493.945(b)(3)(ii)(F) from § 493.1449(k) to 493.1449(e).

- the regulatory cross-references at § 493.1273(b) from § 493.1449(l) to 493.1449(f) and from 493.1449(m) to 493.1449(g).

- the regulatory cross-reference at § 493.1274(c)(1)(i)(A) from § 493.1449(k) to 493.1449(e).

- the regulatory cross-reference at § 493.1417(a) from § 493.1405(b)(3)(i) to 493.1405(b)(3).

- the regulatory cross-reference at § 493.1451(c) from § 493.1449(k)(2) to 493.1449(e)(2).

- the regulatory cross-reference at § 493.1455(a) from §§ 493.1443(b)(3)(i) to 493.1443(b)(3) and from 493.1443(b)(6) to 493.1443(b)(5).

- the regulatory cross-reference at § 493.1469(a) from § 493.1449(k) to 493.1449(e).

C. Change to CLIA Requirements for Alternative Sanctions for CoW Laboratories Under § 493.1804(c)(1)

As discussed in section I.C. of the proposed rule, we proposed amending § 493.1804(c)(1) by removing the phrase "(CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)".

We received public comments on these proposals at § 493.1804(c)(1). The following is a summary of the public comments we received and our responses.

Comment: Several commenters supported the proposed amendment to allow alternative sanctions for CoW laboratories.

Response: We appreciate the commenters' support and are finalizing to remove the phrase "Except for a condition level deficiency under § 493.41 or § 493.1100(a), CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not routinely inspected for compliance with condition-level requirements." As previously discussed, the language "Except for a condition level deficiency under § 493.41 or § 493.1100(a)" was added in the Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency interim final rule with comment period and was only effective during the PHE. Consistent with the finalized amendment to remove the current parenthetical § 493.1804(c), this language will also be deleted as of the effective date of this final rule.

After consideration of the comments received, we are finalizing the proposed amendment at § 493.1804(c)(1).

D. Delayed Effective Date for Certain Regulations Revised in this Final Rule.

We recognize that time will be needed for laboratories, accreditation organizations, exempt States, and surveyors to implement the revised histocompatibility and personnel requirements. As such we are delaying the effective date of the revisions to the Histocompatibility (§ 493.1278) and Personnel (§§ 493.1359(b)(2), (c), and (d), 493.1405(b), 493.1406, 493.1407(c), 493.1411(b), 493.1423(b), 493.1443(b), 493.1445(c) and (e)(10), 493.1449, 493.1461(c) and (d)(3)(i), 493.1461(e), 493.1462, 493.1463(b)(4), 493.1483 introductory text and (b), 493.1489(b), and 493.1491)) regulations, the other related conforming amendments (§§ 493.945(b)(2), (b)(3)(i), and (b)(3)(ii)(C) and (F), 493.1273(b), 493.1274(c)(1)(i)(A), 493.1417(a), 493.1451(c), 493.1455(a), and 493.1469(a)), and the amendments to the Definitions (§ 493.2) for *continuing education (CE) credit hours, doctoral degree, experience directing or supervising, laboratory training or experience,* and *midlevel practitioner* until December 28, 2024. The delayed effective date reflects the timeframe that we

believe the laboratories, accreditation organizations, exempt States, and surveyors will need to adopt and implement these revised regulations.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the proposed rule, we solicited public comment on each of the section 3506(c)(2)(A) required issues for the following sections of this document that contain information collection requirements (ICRs).

A. CLIA Fees

This portion of the final rule does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.).

B. Histocompatibility, Personnel, and Alternative Sanctions

1. Laboratory Costs to Update Policies and Procedures

We expect that the 33,747 CoC and CoA laboratories would incur costs for the time needed to review the revised personnel regulations and update their policies and procedures to be in compliance. The total one-time burden per laboratory to review and update affected policies and procedures is 5 to 7 hours (33,747 x 5 or 7). A management level employee (11-9111) would perform this task at an hourly wage of $57.61 per hour as published by the 2021 Bureau of Labor Statistics.[24] The wage rate would be $115.22 to include overhead and fringe benefits. The total cost would range from $19,441,647 to $27,218,305 (33,747 laboratories x 5- or 7-hours x $115.22).

Similarly, we expect that the 27,257 PPM laboratories would incur costs for the time needed to review and update the one change clarifying the requirement for CAs in PPM laboratories. We assume a one-time burden of 0.25 to 0.5 hours per laboratory for this task (27,257 x 0.25 or 0.5 hours). A management level employee (11-9111) would perform this task at an hourly wage of $57.61 per hour as published by the 2021 Bureau of Labor Statistics.[25] The wage rate would be $115.22 to include overhead and fringe benefits. The total cost would range from $785,138 to $1,570,276 (27,257 laboratories x 0.25- or 0.5-hours x $115.22).

The changes to the histocompatibility requirements affect approximately 247 laboratories that perform testing in this specialty. The laboratories may need to make additional changes to their policies and procedures for the histocompatibility updates. We assume a one-time cost of 1 to 2 hours per laboratory for this task (247 x 1 or 2). A management level employee (11-9111) would perform this task at an hourly wage of $57.61 per hour as published by the 2021 Bureau of Labor Statistics.[26] The wage rate would be $115.22 to include overhead and fringe benefits. The total cost would range from $28,459 to $56,919 (247 laboratories x 1- or 2-hours x $115.22).

Subsequent to the issuance of the July 2022 proposed rule (87 FR 44896), we published a 60-day notice in the Federal Register (88 FR 44132) to solicit public comments on the

[24] *https://www.bls.gov/oes/tables.htm.*
[25] *https://www.bls.gov/oes/tables.htm.*
[26] *https://www.bls.gov/oes/tables.htm.*

information collection requirements contained in this section. The revised information collection request was still under development when the proposed rule published. Upon publication of this final rule, the revised ICR will be submitted to OMB under OMB control number: 0938-0612, which expires January 31, 2024.

2. Accreditation Organization and Exempt State Costs to Update Policies and Procedures

Seven approved accrediting organizations and two exempt States have to review their policies and procedures, provide updates and submit the changes to CMS for approval (9 organizations/exempt States x 10 or 15 hours). We assume a one-time cost of 10 to 15 hours to identify the applicable legal obligations and to develop the policies and procedures needed to reflect the new requirements for personnel and histocompatibility. A management level employee (11-9111) would perform this task at an hourly wage of $57.61 per hour as published by the 2021 Bureau of Labor Statistics.[27] The wage rate would be $115.22 to include overhead and fringe benefits. The total cost would range from $10,370 to $15,555 (9 x 10- or 15 hours x $115.22).

Subsequent to the issuance of the July 2022 proposed rule (87 FR 44896), we published a 60-day notice in the Federal Register (88 FR 44132) to solicit public comments on the information collection requirements contained in this section. The revised information collection request was still under development when the proposed rule published. Upon publication of this final rule, the revised ICR will be submitted to OMB under OMB control number: 0938-0686, which expires January 31, 2024.

Table 11 reflects the total burden and associated costs for the provisions included in this final rule.

[27] *https://www.bls.gov/oes/current/oes_nat.htm.*

TABLE 11: Summary of All Costs for Collection of Information in this Final Rule

Information Collection Requests*	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
A. Laboratory Costs to Update Policies and Procedures		
CoC/CoA	+7	$27,218,305
PPM	+0.5	$1,570,276
Histocompatibility	+2	$56,919
B. Accreditation Organization and Exempt State Costs to Update Policies and Procedures	+15	$15, 555
TOTAL	**+24.5**	**+28,861,055**

*All costs reflected in this table are one-time only costs. There are no ongoing costs.

V. Regulatory Impact Analysis

A. Statement of Need

1. CLIA Fees

As discussed in section I. of the proposed rule, when CLIA was enacted and its implementing regulations were finalized in 1992, CLIA fees were established based on estimates as to the average time a survey would take, cost of the surveyor salary per hour, as well as the size of the laboratory (schedules A, B, etc.). As discussed in section II. of the proposed rule, we proposed to increase certain CLIA fees, add new CLIA fees, and institute a biennial fee increase based on our analysis of the overall level of collections relative to the costs of maintaining the CLIA program, which project a shortfall beginning in calendar year 2025.

2. Histocompatibility, Personnel, Alternative Sanctions

This rule finalizes changes to update the CLIA regulations concerning histocompatibility (§ 493.1278), personnel (§§ 493.1351 through 493.1495), and alternative sanctions for laboratories operating under a CoW (§ 493.1804). With few exceptions, no changes have been made to the requirements listed previously in this final rule since the CLIA regulations were finalized in the February 1992 final rule with comment period (57 FR 7002). HHS assessed the need to update the sections addressed in this rule as many changes have occurred in the practice of laboratory medicine since that time, and other parts of the regulations have since been updated to eliminate redundancies and streamline requirements. We based our decision to update the

regulations and incorporate the changes being finalized in this rule in part, upon advice from CLIAC (*www.cdc.gov/cliac/past-meetings.html*), a Federal advisory committee charged with providing recommendations to HHS on revisions needed to CLIA and from solicited public input via the 2018 RFI (83 FR 1004).

Because the specialty of histocompatibility is an evolving area of the clinical laboratory, several changes were made to update and clarify the histocompatibility requirements finalized in the 2003 final rule (68 FR 3640). Since then, there have continued to be advancements in histocompatibility testing. As a result, some requirements have become obsolete and may preclude using current, improved methods and practices. As already mentioned, there have been updates to other parts of the CLIA regulations to eliminate redundancy with general quality system requirements. However, changes to eliminate redundancy have not previously been made in the histocompatibility specialty, which we believe would simplify and streamline the regulations. Thus, we are finalizing the elimination of redundant histocompatibility specialty regulations in this final rule.

Provisions to end a phase-in period, previously included in subpart M, that allowed individuals with an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science to meet the qualification requirements for LDs of high complexity testing, prior to obtaining board certification, were finalized in the 2003 final rule. This rule also revised and expanded the qualifications required for such individuals to direct a laboratory performing high complexity testing. No other changes have been made to clarify or update subpart M since 1992, even though the top 10 laboratory deficiencies have historically continued to include qualification requirements and responsibilities for moderate and high complexity LDs (*https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAtopten.pdf)*. These high numbers of deficiencies may be due, in part, to the redundancy throughout subpart M or to requirements that are unclear, both of which may be an ongoing source of confusion for

laboratories and individuals seeking to determine their qualification status. The number of deficiencies may also be due to laboratories whose directors are on-site infrequently or not at all.

The CLIA requirements at § 493.1804 describe general considerations for the imposition of sanctions under the CLIA program. This includes principal or alternative sanctions described in § 493.1804(c). This section specifies that alternative sanctions are not imposed on laboratories issued a CoW, but discretion is permitted in applying principal or alternative sanctions to laboratories issued other certificate types. Since the CLIA statute at 42 U.S.C. 263a(h) does not make this distinction with respect to alternative sanctions, we found that § 493.1804(c) can be updated to reflect CMS' belief that both alternative sanctions and principal sanctions should be an option in order to create parity for all certificate types. In some cases, we believe the imposition of principal sanctions on CoW laboratories is not appropriate and could create an undue burden on these laboratories for which, unlike laboratories with other certificate types, CMS cannot currently impose alternative sanctions, if appropriate.

In summary, we based our decision to update our regulations at § 493.1278 related to histocompatibility on changes in practice, advice from CLIAC, and responses to the 2018 RFI. We based our decision to update this rule for the personnel requirements in subpart M §§ 493.1351 through 493.1495 on advice from CLIAC, common questions we have received, and responses to the 2018 RFI. This final rule clarifies this subpart by deleting obsolete and redundant regulations and specifying personnel qualifications and responsibilities. We based our decision to update our regulation at § 493.1804(c) to allow for alternative sanctions to be imposed on CoW laboratories on responses received to the 2018 RFI.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980,

Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 amended section 3(f) of Executive Order 12866 to define a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory actions and/or with significant effects as per section 3(f)(1) of $200 million or more in any 1 year. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is not significant per section 3(f)(1) as measured by the $200 million or more in any 1 year, since neither the low estimate of $20,894,051 nor the high estimate of $30,520,189 exceeds the $200 million annual threshold.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that the great majority of clinical laboratories and AOs are small entities, either by being nonprofit organizations or by meeting the Small Business

Administration definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). For purposes of the RFA, approximately 76 percent of clinical laboratories qualify as small entities based on their nonprofit status as reported in the American Hospital Association Fast Fact Sheet, updated January 2022 (*https://www.aha.org/statistics/fast-facts-us-hospitals)*, and 100 percent of the AOs are nonprofit organizations as required in the CLIA regulations at § 493.551(a). Individuals and States are not included in the definition of a small entity. This percentage of small entities encompasses a substantial number of businesses and laboratories that will be affected by this final rule. However, we are unable to find relevant revenue data to compare the final rule's cost on a per small entity basis. AOs do not all provide the same services, PT modules, or analytes. Clinical laboratories provide different levels of testing, including referring some testing to outside laboratories. The changes regarding LDs may not affect laboratories that are already in compliance based on their prior policies, while other laboratories that do not have LDs on site will be impacted at different levels based on the changes required to be in compliance with this final rule. The other changes being finalized will affect some laboratories more than others. Due to the inconsistency of the impact among all the laboratories and the lack of relevant data, we have provided a range of cost estimates as detailed below in the Anticipated Effects section (section C). As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule, and it is anticipated that the benefits obtained by ensuring quality laboratory testing will outweigh the costs (see Tables 12 and 13). While a substantial number of clinical laboratories and AOs are affected by this rule, the impact is not economically significant. Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities. We are voluntarily preparing a Regulatory Impact Analysis, including both a qualitative and quantitative analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital located outside a metropolitan statistical area with fewer than 100 beds. There are approximately 654 small rural hospitals in the United States. Such hospitals often provide limited laboratory services or may refer all their testing to larger facilities. Although we are unable to estimate the number of laboratories that support small rural hospitals, we do not expect that the rule will have a significant impact on small rural hospitals. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold was approximately $177 million. We found that this final rule would not impose an unfunded mandate on States, Tribal governments, and the private sector of more than $177 million annually.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Two States have exempt status, which means we have determined that the State has enacted laws relating to the laboratory requirements that are equal to or more stringent than CLIA requirements, and the State licensure program has been approved by us. With implementation of the final rule, the two States, New York and Washington, would need to update their policies and procedures to maintain their exempt status but would otherwise not incur additional costs. Therefore, this final rule would not have a substantial direct effect on State or local governments, preempt States, or

otherwise have a Federalism implication, and there is no change in the distribution of power and responsibilities among the various levels of government.

We did not receive any comments for the Overall Impact section in the proposed rule.

C. Anticipated Effects

Tables 12 and 13 reflect the estimated impact for the provisions included in this final rule.

TABLE 12: Summary of Estimated Impact for Histocompatibility and Personnel Regulations

Change	Low estimate	High estimate
Laboratories updating policies and procedures related to personnel and histocompatibility	$20,255,244	$28,845,500
Accrediting organizations and exempt States updating policies and procedures related to personnel, histocompatibility, and laboratory director site visit	$10,370	$15,555
Travel for site visits-Driving	$161,719	$727,500
Travel for site visits-Flying	$466,718	$931,634
Total Increased cost	$20,894,051	$30,520,189

TABLE 13: Summary of Estimated Impact for Fee Regulations

Change	Estimate
CLIA Fee Regulations	$24,371,183
Total Increased cost	$24,371,183

1. Fees

The final rule impacts approximately 298,791 CLIA certified laboratories. Certificate of Waiver (CoW) = 235,175; Certificate for Provider-performed Microscopy (PPM) Procedures = 29,717; Certificate of Registration (CoR) = 2,891; Certificate of Compliance (CoC) = 17,694; Certificate of Accreditation (CoA) = 15,935. (Data from Casper 85s 02/07/2022)

a. Two-part Biennial Survey Fees

(1) CoC Laboratories Compliance Survey Fees

Table 14 reflects the national average of compliance fees for each classification of laboratories (schedules) that requires inspection. Specifically, Table 14 represents the national average for each schedule for the current Compliance Survey Fees (noted with a “c”) as paid biennially by laboratories that hold a CoC and the national average for each schedule for the new

Compliance Survey Fees (noted with a "n") that will be paid after the first biennial two-part fee increase of 4.9598 percent along with an across-the-board increase of 18 percent by laboratories that hold a CoC. As discussed in section II. of this final rule, Table 14 shows estimated increases for CoC laboratories subject to the biennial fee increase.

TABLE 14: Two-part Fee for CoC Survey Fees*

Laboratory classification (schedules)	Current average (c)	New average (n) ATB and Biennial Increase= 18% *4.96%	Number of Laboratories per schedule*	Number of Laboratories per schedule divided by 2**
V	$360	$446	6,794	3,397
A	$1,192	$1,477	3,853	1,926.5
B	$1,591	$1,970	143	71.5
C	$1,988	$2,463	1,945	972.5
D	$2,336	$2,894	186	93
E	$2,684	$3,325	1,521	760.5
F	$3,032	$3,755	822	411
G	$3,380	$4,187	520	260
H	$3,728	$4,618	1,771	885.5
I	$4,076	$5,049	204	102
J	$4,408	$5,459	205	102.5

*Number of CoC labs by laboratory classification (schedules) (Data from Certification and Survey Provider Enhanced Reporting (CASPER) 0086S CLIA Laboratories Schedule Counts) Includes CoR labs of application type CoC.
**The fees are biennial; therefore, approximately half the CoC laboratories are affected annually.

(2) CoA Laboratories Validation Survey Fees.

Table 15 shows the national average of the Validation Survey Fee for each schedule of accredited laboratory. Specifically, Table 15 represents the national average fees for each schedule for the current Validation Survey Fee (noted with a "c") as paid biennially by laboratories that hold a CoA and the national average for the new Validation Survey Fee (noted with an "n") that will be paid after the first biennial two-part fee increase of 4.9598 percent along with an across-the-board increase of 18 percent by laboratories that hold a CoA. As discussed in section II. of this final rule, Table 15 shows estimated increases for CoA laboratories subject to the biennial fee increase.

TABLE 15: Two-part fee for Certificate of Accreditation (CoA) Validation Survey Fees*

Laboratory classification (schedules)	Current average (c)	New average (n) ATB and Biennial Increase= 18% *4.96%	Number of laboratories per schedule*	Number of Laboratories per schedule divided by 2**
V	$18	$22	2,174	1,087
A	$60	$74	2,538	1,269
B	$80	$98	129	64.5
C	$99	$123	1,771	885.5
D	$117	$145	175	87.5
E	$134	$166	1,577	788.5
F	$152	$188	876	438
G	$169	$209	5802	291
H	$186	$231	3,077	1,538.5
I	$204	$252	1,123	561.5
J	$220	$273	1,913	956.5

*Number of CoA labs by laboratory classification (schedules) (Data from CASPER 0086S CLIA Laboratories Schedule Counts dated 10/01/2019-09/30/2021) Includes CoR labs of application type CoA.

**The fees are biennial; therefore, approximately half the CoA laboratories are affected annually.

(3) Certificate of Waiver (CoW) Waived Test Categorization Certificate Fee

Table 16 shows the additional fee to be added to Certificates of Waiver (CoW) to offset program obligations to FDA for its role in the categorization of tests and test systems as waived. Specifically, Table 16 represents the certificate fee (noted with a "c") as paid biennially by laboratories that hold a CoW and the new certificate Fee (noted with an "n") that will be paid by laboratories that hold a CoW. As discussed in section II. of this final rule, Table 16 reflects a total increase of $25 as each laboratory's part of the Waived test categorization fee. This table also takes into account the first biennial two-part fee increase of 4.9598 percent along with an across-the-board increase of 18 percent.

TABLE 16: Certificate of Waiver (CoW) Waived Test Categorization Fee*

Type of CLIA certificate	Current Fee (c)	New Fee (n) based on $25 CoW increase with the ATB and Biennial Increase of 18% *4.96%
Certificate of Waiver (CoW)	$180	$248

*Total CoW lab estimate going into FY 2024 is 235,175/2 = 117,588. The fees are biennial; therefore, approximately half the CoW laboratories are affected annually.

(4) Two-part Biennial Certificate Fees

Table 17 shows the national average of the certificate fee for each schedule for the CoC and CoA laboratories and shows the CoW, PPM, and CoR certificate fees. Specifically, Table 17 represents the national average fees for each schedule for the CoC and CoA Certificate Fee and the CoW, PPM, and CoR (noted with a "c") as paid biennially by laboratories that hold a CoC, CoA, CoW, PPM, or CoR and the national average fees for each schedule for the new CoC and CoA Certificate Fee and the CoW, PPM, and CoR (noted with an "n") that will be paid after the first biennial two-part fee increase of 4.9598 percent with an 18 percent across the board increase by laboratories that hold a CoC, CoA, CoW, PPM, or CoR. As discussed in section II. of this final rule, Table 17 reflects estimated increases for all laboratory types subject to the biennial fee increase.

TABLE 17: Two-part Biennial Certificate Fee

Type of CLIA Certificate	Laboratory schedule	Current fee (c)	New average (n) ATB and Biennial Increase = 18% *4.96%	Number of laboratories*		Number of Laboratories divided by 2**	
Certificate of Waiver (CoW)	Not applicable	$180.00	$248.00 *	235,175		117,587.5	
Certificate for Provider-performed Microscopy (PPM) Procedures	Not applicable	$240.00	$297	29,717		14,858.5	
				CoC	CoA	CoC	CoA
Certificate of Compliance (CoC) and Certificate of Accreditation (CoA)	V	$180.00	$223	6,794	2,174	3,397	1,087
CoC and CoA	A	$180.00	$223	3,853	2,538	1,926.5	1,269
CoC and CoA	B	180.00	$223	143	129	71.5	64.5
CoC and CoA	C	$516.00	$639	1,945	1,771	972.5	885.5
CoC and CoA	D	$528.00	$654	186	175	93	87.5
CoC and CoA	E	$780.00	$966	1,521	1,577	760.5	788.5
CoC and CoA	F	$1,320.00	$1,635	822	876	411	438
CoC and CoA	G	$1,860.00	$2,304	520	582	260	291
CoC and CoA	H	$2,448.00	$3,032	1,771	3,077	885.5	1,538.5
CoC and CoA	I	$7,464.00	$9,244	204	1,123	102	561.5
CoC and CoA	J	$9,528.00	$11,801	205	1,913	102.5	956.5
Certificate of Registration (CoR)	Not applicable	$150	$184	2891		1,445.5	

*CoW $248 includes the 4.96% and 18% Increases +$25.
**Number of laboratories from CASPER 0086S CLIA Laboratories Schedule Counts.
***The fees are biennial; therefore, approximately half of the CoA laboratories are affected annually.

b. New Replacement and Revised Fees

Table 18 shows the cost of the replacement and revised certificate fees for each certificate type. These fees have not been charged prior to this rule.

TABLE 18: CLIA Replacement and Revised Certificates FY2019*

Certificate type	Number of Replacement Certificates issued in FY2019	Cost of Replacement Certificate	Number of Revised Certificates issued in FY2019	Cost of Revised Certificate
CoC	259	$75	515	$150
CoW	2,824	$75	6,985	$95
CoA	496	$75	505	$150
PPM	525	$75	984	$95
Total:	4104	$75	8989	$150

*Number of Replacement and Revised Certificates FY2019 (Data from CASPER 0104D CLIA 116 Activity report).

c. New Additional Fees

Table 19 shows the cost of the additional fees added by this final rule. These fees are only paid by laboratories with substantiated complaint surveys, unsuccessful performance of PT, or follow-up surveys for the determination of correction of deficiencies found on an original survey.

TABLE 19: New Additional Fees

Fees	Affected CLIA Certificate type(s)	Total Number of Affected Laboratories *	Hourly Cost	Occupation	Hours		Range of Cost Estimate for new fees per incident	
					Low	High	Low Estimate	High Estimate
Substantiated Complaints	All Laboratory types	56	$174.78[1]	13-1041 43-1011 43-9199	5.00	184.75	$874	$32,291
Unsuccessful Proficiency Testing (PT)	Certificate of Compliance (CoC) laboratories	1,308	$174.78	13-1041 43-1011 43-9199	1.25	32.25	$218	$5,637
Follow-up Surveys[2]	Certificate of Compliance (CoC) & Certificate of Accreditation (CoA) laboratories	225	$174.78[2]	13-1041 43-1011 43-9199	8.65	19.08	$1,512	$3,335
Total Estimated Cost							$2,604	$41,263

*Total number of affected laboratories is based on actual numbers from FY2019; Data from CASPER reporting system.
[1]$75.11 hourly rate includes $36.45 (13-1041: Compliance Officer) + $30.47 (43-1011: First-Line Supervisors of Office and Administrative Support Workers) + $20.47 (43-9199: Office and Administrative Support Workers, All Other). The wage rate would be doubled to $174.78 to include overhead and fringe benefits. Data from the Department of Labor *U.S. Bureau of Labor Statistics.*
[2]Includes Follow-up surveys on CoC and CoA laboratories and for Addition of Specialties.

2. Histocompatibility, Personnel, Alternative Sanctions

This final rule could impact all of the 319,487 CLIA-certified laboratories (accessed from the CMS Quality Improvement Evaluation System (QIES) database September 2022) to some

extent. The changes to the personnel requirements will impact 33,747 CoC and CoA laboratories, as well as 27,257 PPM Certificate laboratories. The histocompatibility changes will impact 247 CoC and CoA laboratories certified for this specialty; and the allowance for alternative sanctions could impact 243,951 CoW laboratories only if they are found to be out of compliance with CLIA and subject to sanctions. The final rule will also impact the seven CLIA-approved AOs and two exempt States. Although complete data are not available to calculate all estimated costs and benefits that would result from the changes in this rule, we are providing an analysis of the potential impact based on available information and certain assumptions. Implementation of these requirements will result in changes that are anticipated to have both quantifiable and non-quantifiable impacts on laboratories, AOs, and exempt States, as specified previously in this final rule. In estimating the quantifiable impacts, we include costs to CoC, CoA, and PPM laboratories that will result from the need to update policies and procedures. We also estimate costs for travel expenses that laboratories may incur to meet the requirement to have a LD on-site at least once every 6 months. For quantifiable impacts on AOs and exempt States, we estimate the costs for updating their policies and procedures to reflect the new requirements for personnel and histocompatibility.

a. Quantifiable Impacts

(1) Laboratory Costs to Update Policies and Procedures

We expect that the 33,747 CoC and CoA laboratories will incur costs for the time needed to review the revised personnel regulations and update their policies and procedures to be in compliance with them. We assume a one-time burden of 5 to 7 hours per laboratory to review and update affected policies and procedures, and we assume the person performing this task would be a management level employee paid $115.22 per hour (wages, salary and benefits; (*www.bls.gov/oes/tables.htm*)). Therefore, we estimate the one-time costs for CoC and CoA laboratories to update policies and procedures to comply with the revised personnel requirements will range from $19,441,647 to $27,218,305 (see Table 20).

Similarly, we expect that the 27,257 PPM laboratories will incur costs for the time needed to review and update the one change clarifying the requirement for CAs in PPM laboratories. We assume a one-time burden of 0.25 to 0.5 hours per laboratory for this task, also to be performed by a management level employee paid $115.22 per hour (wages, salary and benefits). Therefore, we estimate the one-time costs for PPM laboratories to update the single revised policy and procedure to comply with the personnel requirements will range from $785,138 to $1,570,276 (see Table 20).

The changes to the histocompatibility requirements when this rule is implemented will affect approximately 247 laboratories that perform testing in this specialty (QIES database December 16, 2022). While these laboratories are included in the calculations discussed previously in this final rule, they may need to make additional changes to their policies and procedures for the histocompatibility updates. We assume a one-time burden of one to two hours per laboratory for this task, as described previously in this final rule. Therefore, the laboratory costs for updating policies and procedures related to histocompatibility will range from $28,459 to $56,919 (see Table 20).

(2) Accreditation Organization and Exempt State Costs to Update Policies and Procedures

As a result of this final rule, seven approved accrediting organizations and two exempt States will have to review their policies and procedures, provide updates and submit the changes to us for approval. We estimate a one-time burden of 10 to 15 hours to identify the applicable legal obligations and to develop the policies and procedures needed to reflect the new requirements for personnel and histocompatibility. We assume the person performing this review will be a management level employee paid $115.22 per hour (wages, salary and benefits). Therefore, we estimate the costs for accrediting organizations and exempt States to update their policies and procedures will range from $10,370 to $15,555 (see Table 20).

TABLE 20: Estimated Costs to Update Policies and Procedures

Regulation Change	Affected Group	Total Number of Affected Groups	Hourly Cost	Hours		Range of Cost Estimate for Personnel and Histocompatibility Changes	
				Low	High	Low Estimate	High Estimate
Personnel	CoC & CoA Laboratories	33,747	$115.22	5	7	$19,441,647	$27,218,305
	PPM Laboratories	27,257	$115.22	0.25	0.50	$785,138	$1,570,276
Histocompatibility	CoC & CoA Laboratories	247	$115.22	1	2	$28,459	$56,919
Personnel, Histocompatibility	Accrediting Organizations and Exempt States	9	$115.22	10	15	$10,370	$15,555
Total Increased Cost						$20,265,614	$28,861,055

(3) Laboratory Costs for On-site Laboratory Director Requirement

Estimating the potential travel costs for LDs to meet the on-site requirement is complex, due to wide variation in the numbers of individuals who might incur travel costs, variation in the distances traveled and modes of transportation used, and variation among already existing State and accreditation requirements for LDs to be on-site at some frequency. In addition, we had limited available data on which to base our assumptions. Therefore, we used a conservative approach in calculating our estimates and believe the estimates described below may be higher than actual costs that will be incurred.

In general, 10 States, one territory, and three out of seven AOs currently have some requirement for on-site visits by LDs, although the required frequencies vary. Ten States, including the exempt State of New York, plus the territory of Puerto Rico currently have requirements that are as stringent or more stringent than the provision that requires a LD to be on-site at least once every 6 months. Therefore, we have not counted CoC laboratories in these 10 States or in Puerto Rico among those that would be impacted by the requirement for on-site LD visits. One accrediting organization American Association of Blood and Biotherapies (AABB) now requires on-site LD visits at least once a quarter. However, AABB only accredits 226 laboratories, or approximately 1.5 percent, of all accredited laboratories (QIES database,

September 2022). Some of these laboratories are part of a hospital or other health care system that has laboratory specialties accredited for CLIA purposes by one or more of the other accrediting organizations, and therefore, will be impacted by the requirement for on-site LD visits. Since we do not have data to determine the number of such laboratories that are only accredited by AABB and already are meeting this requirement, and the number is likely to be relatively small, we are not adjusting the number of impacted laboratories based on AABB accreditation.

In the 40 States, four territories, and the District of Columbia, where the LD is not required to be on-site at least twice per year, 25,867 CoC and CoA laboratories (QIES, December 16, 2022) may not currently meet this requirement and may incur travel costs to comply with it. We have not adjusted this number where the provision was partially met, since no frequency was specified for CoC laboratories in three additional States, CoA laboratories under two additional accrediting organizations, or laboratories in the exempt State of Washington.

We assume that in most instances, the LD is on-site daily or more frequently than twice per year. Based on a review of State and AO information, discussed earlier in the preamble for this rule, we assume that between 5 percent (1,293) and 20 percent (5,173) of the CoC and CoA laboratories would need their LDs to travel twice a year to meet this requirement. For our estimate, we assumed this travel would include a combination of two modes of transportation, driving and flying. For the low estimate, we assumed that 1 percent of the 25,867 laboratories, or 259, would compensate their directors for flights while 4 percent, or 1,035 laboratories, would compensate them for their mileage to drive. For the high estimate, we assumed that, at most, 2 percent of the 25,867 laboratories, or 517, would compensate their LD for flying and that 18 percent, or 4,656 laboratories, would compensate for driving.

- *Driving*: We believe most LDs would drive fewer than 250 miles round trip to reach the laboratories they direct. We assume these LDs would drive to the location, conduct business,

and return home the same day. We base our calculations for driving on the maximum estimated distance of 250 miles at $0.625 cents per mile (government travel reimbursement rates for mileage (*https://www.gsa.gov/travel-resources*)) for a maximum cost of $156.25 per trip. This may be an over-estimate since we believe not all the individuals who drive would travel 250 miles round trip. Based on the low estimate of 1,035 laboratories incurring costs for driving and our high estimate of 4,656 laboratories incurring costs for driving, our calculated cost for driving is estimated to range from $161,719 to $727,500 (see Table 21).

- *Flying*: Our estimates for the cost of flying assume that in these cases, travel to a remote site will be necessary. We believe basing it on travel to a remote site will over-estimate the cost since in many locations, although the LD may fly to reach their destination, they would not travel to remote locations and the travel costs would be less. However, we do not know the specific circumstances for which flying would be required. We estimated the maximum airfare for this travel to be $1500 and lodging costs to average $151.00 per night (based on the average of 100 hotel rates throughout the U.S. for 2020) (*https://ik.imgkit.net/3vlqs5axxjf/BTN/uploadedfiles/9_Microsites/Corporate_Travel_Index/CTI_2021/US_Diem/3-4_USHotelDetail.pdf).* We assumed lodging for two nights would be needed. Therefore, the total estimated cost for one trip would be $1,500 flight + $302.00 lodging or $1,802.00 per trip. Based on the low estimate of 259 laboratories incurring costs for remote travel and our high estimate of 517 laboratories incurring costs for remote travel, the range for laboratory costs for flying to on-site visits would be between $466,718 and $931,634 (see Table 21). Based on these assumptions for both driving and flying, we estimate the total cost for laboratories to compensate travel for the LD ranges from $628,437 to $1,659,134.

TABLE 21: Estimated Travel Costs to Meet On-site Laboratory Director Requirement

Regulation Change	Affected Group	Total Number of Affected Group		Airfare Cost ($1,500)	Hotel Cost ($151/2 nights)	Driving Cost ($0.625/mile*250 miles)	Total Impact for Personnel and Histocompatibility Regulation Changes	
On-Site Laboratory Director	CoA and CoC Laboratories	Low Estimate	High Estimate				Low estimate	High estimate
	Driving	1,035 (4%)	4,656 (18%)	NA	NA	$156.25	$161,719	$727,500
	Flying	259 (1%)	517 (2%)	$1,500	$302	N/A	$466,718	$931,634
Total Increased Cost							$628,437	$1,659,134

TABLE 22: Estimated Impact for Histocompatibility and Personnel Regulations

Change	Low estimate	High estimate
Laboratories updating policies and procedures related to personnel and histocompatibility*	$20,255,244	$28,845,500
Accrediting organizations and exempt States updating policies and procedures related to personnel, histocompatibility, and laboratory director site visit	$10,370	$15,555
Travel for site visits-Driving	$161,719	$727,500
Travel for site visits-Flying	$466,718	$931,634
Total Increased cost	$20,894,051	$30,520,189

* Low/high estimates represent the sum of estimates in Table 20 to update policies and Table 21 to estimate travel costs.

We did not receive any public comments on the discussion of the Anticipated Effects, Quantifiable Impacts, section in the proposed rule.

b. Results

We estimate that the overall impact of adding requirements for the changes in personnel, histocompatibility, and travel for LD on-site visits would range from $20,894,051 to $30,520,189 in the first year (see Table 22).

For each of the changes, Table 23 shows the projected range of cost estimates on an annual basis for 5 years starting in 2023. We assume costs for updating policies and procedures will be one-time costs that are only incurred in 2023. We assume the travel costs will be ongoing and will not change significantly over the 5-year period. The maximum cost estimate of approximately $30.5 million for the first year based on 2023 costs and approximately $1.7 million for subsequent years is not considered a significant economic impact. This final rule does not reach the economic threshold and thus is not considered a major rule.

TABLE 23: Five-Year Projection for Total Estimated Annual Costs for Personnel Regulations

Change	2023		2024		2025		2026		2027	
	Low	**High**	**Low**	**High**	**Low**	**High**	**Low**	**High**	**Low**	**High**
Policies and procedures-Laboratories*	$20,255,244	$28,845,500	$0	$0	$0	$0	$0	$0	$0	$0
Policies and procedures-Accrediting organizations and Exempt States	$10,370	$15,555	$0	$0	$0	$0	$0	$0	$0	$0
Travel-Driving	$161,719	$727,500	$161,719	$727,500	$161,719	$727,500	$161,719	$727,500	$161,719	$727,500
Travel-Flying	$466,718	$931,634	$466,718	$931,634	$466,718	$931,634	$466,718	$931,634	$466,718	$931,634
Total Increased cost	**$20,894,051**	**$30,520,189**	**$628,437**	**1,659,134**	**$628,437**	**1,659,134**	**$628,437**	**1,659,134**	**$628,437**	**1,659,134**

* Low/high estimates represent the sum of estimates in Table 20 to update policies and Table 21 to estimate travel costs.

We did not receive any comments for the Anticipated Effects, Result, section in the proposed rule.

c. Non-quantifiable Impacts and Benefit

(1) CLIA Fees

We stated in the proposed rule that CMS has limited knowledge of the non-quantifiable impacts and benefits and requested public comment on this topic.

We note that we did not receive any comments for the Anticipated Effects, Non-quantifiable Impacts and Benefit, CLIA Fees section in the proposed rule.

(2) Histocompatibility, Personnel, Alternative Sanctions

With implementation of this final rule for histocompatibility, personnel, and alternative sanctions several non-quantifiable impacts, most of which are considered benefits, will result for laboratories, accrediting organizations, and exempt States concerning changes in the requirements for personnel, histocompatibility, and alternative sanctions for CoW laboratories.

Many personnel changes in this rule will decrease the burden and provide greater flexibility for laboratories by increasing the number of eligible candidates for some personnel categories by expanding and clarifying the qualifying degrees. Examples of the provisions that will increase the number of qualified candidates for personnel categories include the addition of: clinical nurse specialists and certified registered nurse anesthetists in the definition of midlevel practitioners, a bachelor's degree in respiratory therapy as a possible qualifying degree as a TC and TP for moderate and high complexity blood gas testing, and an associate or bachelor of nursing degree as a qualifying degree for moderate complexity TP. Adding these options as qualifying degrees does not preclude the need for individuals to meet clinical laboratory training and experience requirements.

This rule will decrease burden, increase flexibility for laboratories, and streamline regulations by aligning the technical supervisor qualifications for laboratories performing immunohematology with those of other specialties such as hematology. Instead of limiting those

qualified to serve as a technical supervisor in immunohematology to individuals with a doctor of medicine or doctor of osteopathy degree and appropriate certification and experience, individuals may also qualify with a doctoral, master's, or bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology, or medical laboratory science and 1, 2, or 4 years applicable experience, respectively. These changes streamline the regulations and could increase a laboratory's ability to find qualified personnel, especially in rural areas. As it is not possible to predict the pathway a laboratory will use to qualify individuals when hiring personnel, we cannot quantify the impacts that would result with this rule.

Several other changes in this rule will impact laboratories and their personnel. However, we do not have data to quantify the impact. The qualification requirement for completing 20 CE credit hours, to cover LD responsibilities as defined in the regulations, prior to serving as an LD will apply to LDs for both moderate and high complexity testing except for those doctors of medicine, osteopathy, or podiatry who are certified by the American Board of Pathology, the American Osteopathic Board of Pathology, or other boards approved by HHS. Although there will be costs associated with obtaining these credits, currently employed LDs, at the effective date of the final rule, will not be required to obtain the 20 CE credit hours to retain their employment status. In the future, only one of several qualification routes for LDs will require the 20 CE credit hours. Accordingly, we cannot predict the number of laboratories that will choose to hire a LD through this qualification route. The impact of removing physical science degrees as qualifying degrees for any personnel categories is lessened because these individuals may still qualify if they have the required coursework and experience. In addition, laboratory personnel employed in their position on the effective date of the final rule, will continue to qualify under the applicable grandfather provision as long as they remain continuously employed in their positions.

The changes to the histocompatibility requirements in this rule will impact laboratories, accrediting organizations, and exempt States. It will streamline the histocompatibility

requirements and remove those that are no longer relevant based on current testing practices, adding flexibility for laboratories and removing perceived barriers to current practices. It will remove specific, redundant requirements and replace them with those covered in general under §§ 493.1251, 493.1252, 493.1256, and 493.1445. This will simplify the requirements related to procedure manuals; test systems, equipment, instruments, reagents, materials, and supplies; control procedures; and LD responsibilities. We believe these impacts will decrease the burden and positively affect laboratories certified to perform testing in this specialty, as well as health care providers and patients.

Last, concerning the alternative sanctions provision, the final rule will allow us discretion in imposing alternative sanctions (that is, civil money penalties (CMP), directed plan of correction, directed portion of a plan of correction, and on-site State monitoring), rather than only being able to impose principal sanctions (that is, revocation, suspension, limitation of the CLIA certificate), in CoW laboratories, if appropriate. We believe this will increase flexibility, decrease potential burden while moving those laboratories toward compliance, and have no added economic impact on CoW laboratories. As previously described, this regulatory change could decrease the burden for sanctions imposed for improper proficiency testing referral. Although we have no data indicating that principal sanctions have been imposed on CoW laboratories for this reason in the past, if it occurred in the future, the ability to impose alternative sanctions, if appropriate, would be less punitive and potentially decrease any quantifiable economic impact. At this time, we cannot quantify what that impact would be.

We did not receive any comments for the Anticipated Effects, Non-quantifiable Impacts and Benefit, Histocompatibility, Personnel, Alternative Sanctions, section in the proposed rule.

D. Alternatives Considered

1. CLIA Fees

We considered multiple options prior to the proposed rule, including limiting across-the-board increase to varying percentages and timeframes required to achieve reasonable carryover

targets for the CLIA program as a whole. We discussed multiple options in the December 31, 2018 notice with comment period (NC), including limiting the increase to varying percentages and timeframes across a single fee type, specifically Compliance Fees. When preparing the July 2022 proposed rule, we reviewed the alternatives in the NC to see if they were viable moving forward. The approach proposed was the best scenario for longevity for maintaining the fiscal solvency of the user-funded CLIA program. We have determined that 2 quarters worth of obligations were a reasonable carryover target based on program funding requirements and the time to accumulate and make available current year fee collections. We have also decided to build up to the carryover target over a 3-year period to avoid either overcharging or undercharging. For example, we considered the following options:

- Setting various one-time dollar level fee increases for CoW laboratories.
- Setting various percentage increases for the one-time across-the-board increase.

Public comments received from the December 31, 2018 notice (83 FR 67723) with comment period (Medicare Program; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees[28]) and 2022 proposed rule were considered during rulemaking.

We did not receive any comments for the Alternatives Considered, CLIA Fee section in the proposed rule.

2. Histocompatibility, Personnel, Alternative Sanctions

Several alternatives were considered in developing these changes to the histocompatibility, personnel, and alternative sanctions requirements under CLIA. In all cases, one option would be to leave the regulations as written. However, because many of the changes being finalized for histocompatibility and personnel resulted from public input via the 2018 RFI and recommendations made by CLIAC and will add flexibility, remove redundant or obsolete requirements, clarify and streamline the regulations, and decrease burden while maintaining laboratory quality, making these changes would be preferable. Also, the requirement to allow

[28] 83 FR 67723, December 31, 2018 (*https://www.govinfo.gov/content/pkg/FR-2018-12-31/pdf/2018-28359.pdf).*

alternative sanctions to be imposed on CoW laboratories aligns the regulations with the CLIA statute; therefore, no other options were considered.

Regarding the histocompatibility requirements, we initially considered only removing the crossmatch regulatory requirement at § 493.1278(f)(2) which was perceived as a barrier to current practice with kidney transplantation. However, we decided to obtain input from interested parties to identify any concerns regarding crossmatching and other current regulatory requirement under the histocompatibility specialty. Our purpose for seeking input from interested parties through CLIAC and the 2018 RFI was to obtain information on whether the current histocompatibility requirements, including requirements for crossmatching, needed to be revised from when CLIA regulations were published in 1998 and 2003 to reflect the current practice. Our revision in this final rule reflects our attempt to address the input from interested parties and are intended to reflect the current practices as provided to CMS by interested parties through the 2018 RFI and CLIAC.

One of the personnel requirements in this rule is to require that LDs of moderate and high complexity testing, who are qualified through an educational pathway other than being a certified anatomic or clinical pathologist, have at least 20 CE credit hours related to their LD responsibilities. We considered requiring this of all LDs. However, since pathologists obtain this education as part of their education and training, it would be redundant and could increase costs to require this, although we do not have data to estimate what those costs would be since we do not know how many LDs would qualify using this pathway. We believe it is appropriate to finalize this requirement for other LD qualification routes. This information is critical for fulfilling LD responsibilities and is not always included in education and training for alternative qualification pathways.

Another LD requirement in this final rule is on-site visits to the laboratory at least once every 6 months, with at least a 4-month interval between on-site visits. We considered requiring these visits at a different frequency or not adding this requirement. However, surveyors reported

that laboratories in which the director is not on-site tend to have more issues and citations when inspected, and 10 States, the territory of Puerto Rico, and one of the CLIA-approved AOs already require LD to be on-site at least once every 6 months. As a result, CLIAC recommended that LDs make and document at least two reasonably spaced on-site visits per year to supplement other interactions with staff and verify that the laboratory complies with laws and regulations. We agree with the CLIAC recommendation that two on-site visits per year is an appropriate frequency to achieve the intended improvement in laboratory compliance without adding a significant burden to laboratories. We will monitor this impact once the rule is finalized. Requiring these visits at a greater frequency and keeping all other factors the same would increase total projected costs per year. While requiring on-site visits only once per year would reduce estimated costs, it could delay the potential time it takes to identify laboratory issues that could ultimately result in patient harm. A third personnel requirement in this rule for which we considered various options is the expansion of the definition of midlevel practitioners to include certified registered anesthetists, and clinical nurse specialists as personnel qualified to serve as a LD or TP in PPM laboratories. Currently, this definition is limited to nurse midwives, nurse practitioners, or physician assistants, licensed by the State where the individual practices, if required in the State where the laboratory is located. We considered not expanding this definition or expanding it to include only one of the categories. However, certified registered anesthetists and clinical nurse specialists are both considered advanced practice registered nurses, as are certified nurse midwives and nurse practitioners. All four categories require at least a master's degree in nursing, and all may play a role in providing primary and preventive care services to the public. This may include performing the microscopic examinations required under PPM. As there is no expected cost-increasing impact of adding either of these nursing categories to the midlevel practitioner definition, and the change will increase flexibility and access to PPM testing, we are including it in the final rule.

We did not receive any comments for the Alternatives Considered, the Histocompatibility, Personnel, Alternative Sanctions section in the proposed rule.

E. Conclusion

1. CLIA Fees

Although the effect of the changes will increase laboratory costs, implementation of these changes would be negligible in terms of workload for laboratories as these fee increases are operational and technical in nature and do not require additional time to be spent by laboratory employees.

2. Histocompatibility, Personnel, Alternative Sanctions

We estimate that the cost to laboratories, accrediting organizations, and exempt States to comply with the changes in the final rule would range between $20,894,051 and $30,520,189 in 2023 dollars for the first year and between $628,437 and $1,659,134 in subsequent years. Although the requirements will increase laboratory costs, the implementation of the final rule will streamline and simplify regulations, add flexibility in laboratory hiring practices, ensure that the LD is on-site at least twice per year, and align histocompatibility testing with current methods and practices. This final rule will also allow alternative sanctions to be imposed on CoW laboratories.

We have determined that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact in the operations of a substantial number of small rural hospitals. For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 11, 2023.

Mandy K. Cohen, MD, MPH, Director of the Centers for Disease Control and Prevention, approved this document on November 11, 2023.

List of Subjects in 42 CFR Part 493

Administrative practice and procedure, Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 493 as set forth below:

PART 493-LABORATORY REQUIREMENTS

1. Effective January 27, 2024, the authority citation for part 493 is revised to read as follows:

Authority: 42 U.S.C. 263a, 1302, 1395x(e), 1395x(s)(3) and (s)(17).

2. Effective January 27, 2024, amend § 493.2 by adding definitions for "Replacement certificate" and "Revised certificate" in alphabetical order to read as follows:

§ 493.2 Definitions.

* * * * *

Replacement certificate means an active CLIA certificate that is reissued with no changes made.

* * * * *

Revised certificate means an active CLIA certificate that is reissued with changes to one or more fields displayed on the certificate, such as the laboratory's name, address, laboratory director, or approved specialties/subspecialties. For purposes of this part, revised certificates do not include the issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service.

* * * * *

3. Effective December 28, 2024, further amend § 493.2 by:

a. Adding definitions for “Continuing education (CE) credit hours”, “Doctoral degree”, “Experience directing or supervising”, and “Laboratory training or experience” in alphabetical order; and

b. Revising the definition of “Midlevel practitioner”.

The additions and revision read as follows:

§ 493.2 Definitions.

* * * * *

Continuing education (CE) credit hours means either continuing medical education (CME) or continuing education units (CEUs). The CE credit hours must cover the applicable laboratory director responsibilities and be obtained prior to qualifying as a laboratory director.

* * * * *

Doctoral degree means an earned post-baccalaureate degree with at least 3 years of graduate level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science, medical laboratory science, or medical technology. For purposes of this part, doctoral degrees do not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatric medicine (DPM), doctors of veterinary medicine (DVM) degrees, or honorary degrees.

* * * * *

Experience directing or supervising means that the director or supervisory experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b).

* * * * *

Laboratory training or experience means that the training or experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b).

Midlevel practitioner means a nurse midwife, nurse practitioner, nurse anesthetist, clinical nurse specialist, or physician assistant licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

* * * * *

§ 493.557 [Amended]

4. Effective January 27, 2024, amend § 493.557 in paragraph (b)(4) by removing the reference "§§ 493.645(a) and 493.646(b)" and adding in its place the reference "§§ 493.649(a) and 493.655(b)".

§ 493.575 [Amended]

5. Effective January 27, 2024, amend § 493.575 in paragraph (i) by removing the reference "§§ 493.645(a) and 493.646(b)" and adding in its place the reference "§§ 493.649(a) and 493.655(b)".

6. Effective January 27, 2024, § 493.638 is revised to read as follows:

§ 493.638 Certificate fees.

(a) *Basic rule.* Laboratories must pay a fee that covers the costs incurred for the issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service, and other direct administrative costs, as applicable. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act.

(1) For registration certificates, the fee is a flat fee that includes the costs for issuing the certificates, collecting the fees, and evaluating whether the procedures, tests, or examinations listed on the application fall within the testing allowed for the requested certificate.

(2) For a certificate of waiver, the fee includes the costs for issuing the certificate; collecting the fees; evaluating whether the procedures, tests, or examinations listed on the application fall within the testing appropriate for the requested certificate; and determining whether a laboratory test meets the criteria for a waived test.

(3) For a certificate for PPM procedures, the fee includes the costs for issuing the certificate, collecting the fees; and evaluating whether the procedures, tests, or examinations listed on the application meet the criteria for inclusion in the subcategory of PPM procedures.

(4) For a certificate of accreditation, the fee includes the costs for issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and evaluating whether the procedures, tests, or examinations listed on the application fall within the testing appropriate for the requested certificate.

(5) For a certificate of compliance, the fee includes the costs for issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing programs, and evaluating whether the procedures, tests or examinations listed on the application fall within the testing appropriate for the requested certificate.

(b) *Fee amount.* (1) The certificate fee amount is set biennially by HHS. CMS will publish a notice in the **Federal Register** biennially with any adjustments to the fee amounts, including any adjustments due to inflation, in accordance with § 493.680. For certificates of waiver and certificates of PPM, the certificate fee amount is based on the category of test complexity performed by the laboratory. For all other certificate types, the fee amount is based on the category of test complexity performed by the laboratory and schedules or ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, or proficiency testing purposes) and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in paragraph (c) of this section.

(2) Certificate fees are assessed and payable at least biennially.

(3) The amount of the fee payable by the laboratory is the amount listed in the most recent notice published in the **Federal Register** at the time the application, renewal, change in certificate type, or reinstatement is processed by HHS or its designee.

(4) After processing an application for an issuance, renewal, change in certificate type, or

reinstatement of a terminated certificate with a gap in service, HHS or its designee notifies the laboratory of the applicable fee amount.

(c) *Classification of laboratories for purposes of determining the fee amount for certificate types other than certificates of waiver or certificates of PPM*. (1) For purposes of determining a laboratory's classification under this section, a test is a procedure or examination for a single analyte. (Tests performed for quality control, quality assessment, and proficiency testing are excluded from the laboratory's total annual volume.) Each profile (that is, group of tests) is counted as the number of separate procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.

(2) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:

(A) Bacteriology.

(B) Mycobacteriology.

(C) Mycology.

(D) Parasitology.

(E) Virology.

(ii) The specialty of Serology, which includes one or more of the following subspecialties:

(A) Syphilis Serology.

(B) General immunology.

(iii) The specialty of Chemistry, which includes one or more of the following subspecialties:

(A) Routine chemistry.

(B) Endocrinology.

(C) Toxicology.

(D) Urinalysis.

(iv) The specialty of Hematology.

(v) The specialty of Immunohematology, which includes one or more of the following subspecialties:

(A) ABO grouping and Rh typing.

(B) Unexpected antibody detection.

(C) Compatibility testing.

(D) Unexpected antibody identification.

(vi) The specialty of Pathology, which includes the following subspecialties:

(A) Cytology.

(B) Histopathology.

(C) Oral pathology.

(vii) The specialty of Radiobioassay.

(viii) The specialty of Histocompatibility.

(ix) The specialty of Clinical Cytogenetics.

(3) There are 11 schedules of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into one of the 11 schedules in paragraphs (c)(3)(i) through (xi) of this section based on the laboratory's scope and volume of testing:

(i) *Schedule V*. The laboratory performs not more than 2,000 laboratory tests annually.

(ii) *Schedule A*. The laboratory performs tests in no more than three specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laboratory tests.

(iii) *Schedule B*. The laboratory performs tests in at least four specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iv) *Schedule C*. The laboratory performs tests in no more three specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(v) *Schedule D.* The laboratory performs tests in at least four specialties with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(vi) *Schedule E.* The laboratory performs more than 25,000 but not more than 50,000 laboratory tests annually.

(vii) *Schedule F.* The laboratory performs more than 50,000 but not more than 75,000 laboratory tests annually.

(viii) *Schedule G.* The laboratory performs more than 75,000 but not more than 100,000 laboratory tests annually.

(ix) *Schedule H.* The laboratory performs more than 100,000 but not more than 500,000 laboratory tests annually.

(x) *Schedule I.* The laboratory performs more than 500,000 but not more than 1,000,000 laboratory tests annually.

(xi) *Schedule J.* The laboratory performs more than 1,000,000 laboratory tests annually.

7. Effective January 27, 2024, § 493.639 is revised to read as follows:

§ 493.639 Fees for revised and replacement certificates.

(a) If, after a laboratory is issued a certificate, it requests a revised certificate, the laboratory must pay a fee to cover the cost of issuing a revised certificate. The fee for a revised certificate is based on the cost to issue the revised certificate to the laboratory. The fee must be paid in full before the revised certificate will be issued.

(1) If laboratory services are added to a certificate of compliance, the laboratory must pay an additional fee if required under § 493.643(d)(2).

(2) [Reserved]

(b) If, after a laboratory is issued a certificate, it requests a replacement certificate, the laboratory must pay a fee to cover the cost of issuing a replacement certificate. The fee for a replacement certificate is based on the cost of issuing the replacement certificate to the laboratory. The fee must be paid in full before issuing the replacement certificate.

8. Effective January 27, 2024, § 493.643 is revised to read as follows:

§ 493.643 Additional fees applicable to laboratories issued a certificate of compliance.

(a) *Fee requirement.* In addition to the fee required under § 493.638, a laboratory subject to routine inspections must pay a fee to cover the cost of determining program compliance. Laboratories issued a certificate for PPM procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

(b) *Costs included in the fee.* Included in the fee for determining program compliance are costs for evaluating qualifications of laboratory personnel; monitoring laboratory proficiency testing; and conducting onsite inspections of laboratories including: documenting deficiencies, evaluating laboratories' plans to correct deficiencies, creating training programs, training surveyors, and necessary administrative costs.

(c) *Fee amount*. The amount of the fee for determining program compliance is set biennially by HHS.

(1) The fee is based on the category of test complexity and schedules or ranges of annual laboratory test volume and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of determining program compliance as set forth in § 493.638(c).

(2) The fee is assessed and payable biennially.

(3) The amount of the program compliance fee is the amount applicable to the laboratory listed in the most recent notice published in the **Federal Register** at the time that the fee is generated.

(d) *Additional fees.* (1) If a laboratory issued a certificate of compliance has been inspected and follow-up visits are necessary because of identified deficiencies, HHS assesses the laboratory a fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the follow-up visits. HHS revokes the laboratory’s certificate of compliance for failure to pay the assessed fee.

(2) If, after a certificate of compliance is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities. HHS revokes the laboratory's certificate for failure to pay the compliance determination fee.

(3) If it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the laboratory holding a certificate of compliance a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the Government's costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed costs.

(4) Laboratories with a certificate of compliance must pay a fee if the laboratory fails to perform successfully in proficiency testing for one or more specialties, subspecialties, analytes, or tests specified in subpart I of this part, and it is necessary to conduct a desk review of the unsuccessful performance. The additional fee is based on the actual resources and time necessary to perform the desk review. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed costs.

9. Effective January 27, 2024, amend § 493.645 by:

a. Revising the section heading;

b. Removing paragraph (a);

c. Redesignating paragraphs (b) and (c) as paragraphs (a) and (b);

d. Revising newly redesignated paragraph (a); and

e. Adding a paragraph heading for newly redesignated paragraph (b).

The revisions and addition read as follows:

§ 493.645 Additional fees applicable to laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.

(a) *Accredited laboratories.* (1) A laboratory that is issued a certificate of accreditation is assessed an additional fee to cover the cost of performing validation inspections described at § 493.563. All accredited laboratories share in the cost of these inspections. These costs are 5 percent of the same costs as those that are incurred when inspecting nonaccredited laboratories of the same schedule (or range) and are paid biennially by each accredited laboratory whether the accredited laboratory has a validation inspection or not. HHS revokes the laboratory's certificate of accreditation for failure to pay the fee.

(2) If a laboratory issued a certificate of accreditation has been inspected and follow-up visits are necessary because of identified deficiencies, HHS assesses the laboratory an additional fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the follow-up visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the fee.

(b) *Complaint surveys.* * * *

§ 493.646 [Removed]

10. Effective January 27, 2024, § 493.646 is removed.

11. Effective January 27, 2024, § 493.649 is revised to read as follows:

§ 493.649 Additional fees applicable to approved State laboratory programs.

(a) *Approved State laboratory programs.* State laboratory programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, CLIA-exempt laboratories) to verify that standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State’s CLIA-exempt

laboratories if the complaint is substantiated.

(3) The State's pro rata share of general overhead to administer the laboratory certification program under section 353 of the PHS Act.

(b) [Reserved]

12. Effective January 27, 2024, § 493.655 is added to subpart F to read as follows:

§ 493.655 Payment of fees.

(a) Except for laboratories covered by approved State laboratory programs, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

(b) For approved State laboratory programs, HHS estimates the cost of conducting validation inspections as described at § 493.563 within the State on at least a biennial period. HHS or its designee notifies the State by mail of the appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must be made. In addition, if complaint investigations are conducted in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

13. Effective January 27, 2024, § 493.680 is added to subpart F to read as follows:

§ 493.680 Methodology for determining the biennial fee increase.

(a) *General rule.* Except for fees assessed to State laboratory programs approved by HHS, the fee amounts described in this subpart are subject to a biennial increase based on a two-part calculation of the Consumer Price Index-Urban (CPI-U) inflation adjustment and, if applicable, an additional increase as follows:

(1) CMS calculates the inflation rate using the compounded CPI-U over 2 years and, provided that the calculated rate is greater than zero, applies an increase to all fee amounts equal to the calculated rate.

(2) If the total fee amounts, including any increase applied under paragraph (a)(1) of this section, do not match or exceed actual program obligations based on a review of the previous 2 years' obligations, CMS applies an additional across the board increase to each laboratory's fees by calculating the difference between the total fee amounts and actual program obligations.

(b) *Baseline*. Any increase applied under paragraph (a) of this section is incorporated into the baseline fee amounts for any subsequent biennial increase.

(c) *Publication.* Any increase applied under paragraph (a) of this section, including the calculation thereof, will be published as a notice in the **Federal Register**.

14. Effective December 28, 2024, amend § 493.945 by revising paragraphs (b)(2), (b)(3)(i), (b)(3)(ii)(C) introductory text, and (b)(3)(ii)(F) introductory text to read as follows:

§ 493.945 Cytology; gynecologic examinations.

* * * * *

(b) * * *

(2) An individual qualified as a technical supervisor under § 493.1449(b) or (e) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets slide preparations that have not been previously examined must be tested using a test set that has not been previously screened.

(3) * * *

(i) Each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under § 493.1469 or § 493.1483 or functioning as a technical supervisor in cytology qualified under § 493.1449(b) or (e) of this part.

(ii) * * *

(C) Criteria for scoring system for a 10-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (e):

* * * * *

(F) Criteria for scoring system for a 20-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (e):

* * * * *

15. Effective December 28, 2024, amend § 493.1273 by revising paragraph (b) to read as follows:

§ 493.1273 Standard: Histopathology.

* * * * *

(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in § 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under § 493.1449(b), (f), or (g).

* * * * *

16. Effective December 28, 2024, amend § 493.1274 by revising paragraph (c)(1)(i)(A) to read as follows:

§ 493.1274 Standard: Cytology.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(A) A technical supervisor qualified under § 493.1449(b) or (e).

* * * * *

17. Effective December 28, 2024, § 493.1278 is revised to read as follows:

§ 493.1278 Standard: Histocompatibility.

(a) *General.* The laboratory must meet the following requirements:

(1) Use a continuous monitoring system and alert system to monitor the storage temperature of specimens (donor and recipient) and reagents and notify laboratory personnel when temperature limits are exceeded.

(2) Establish and follow written policies and procedures for the storage and retention of specimens based on the specific type of specimen. All specimens must be easily retrievable. The laboratory must have an emergency plan for alternate storage.

(3) If the laboratory uses immunologic reagents to facilitate or enhance the isolation or identification of lymphocytes or lymphocyte subsets, the efficacy of the methods must be monitored with appropriate quality control procedures.

(4) Participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

(b) *Human leukocyte antigen (HLA) typing.* The laboratory must do the following:

(1) Use HLA antigen terminology that conforms to the World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System.

(2) Have available and follow written criteria for determining when antigen and allele typing are required.

(c) *Antibody screening and identification.* The laboratory must make a reasonable effort to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening, identification, and crossmatch.

(d) *Crossmatching.* For each type of crossmatch that a laboratory performs, the laboratory must do the following, as applicable:

(1) Establish and follow written policies and procedures for performing a crossmatch.

(2) Have available and follow written criteria for the following:

(i) Defining donor and recipient HLA antigens, alleles, and antibodies to be tested;

(ii) Defining the criteria necessary to assess a recipient's alloantibody status;

(iii) Assessing recipient antibody presence or absence on an ongoing basis;

(iv) Typing the donor, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable;

(v) Describing the circumstances in which pre- and post-transplant confirmation testing of donor and recipient specimens is required;

(vi) Making available all applicable donor and recipient test results to the transplant team;

(vii) Ensuring immunologic assessments are based on test results obtained from a test report from a CLIA-certified laboratory; and

(viii) Defining time limits between recipient testing and the performance of a crossmatch.

(3) The test report must specify the type of crossmatch performed.

(e) *Transplantation.* Laboratories performing histocompatibility testing for infusion and transplantation purposes must establish and follow written policies and procedures specifying the histocompatibility testing (that is, HLA typing, antibody screening and identification, and crossmatching) to be performed for each type of cell, tissue, or organ to be infused or transplanted. The laboratory's policies and procedures must include, as applicable—

(1) Testing protocols that address:

(i) Transplant type (organ, tissue, cell);

(ii) Donor (living, deceased, or paired): and

(iii) Recipient (high risk vs. unsensitized);

(2) Type and frequency of testing required to support clinical transplant protocols; and

(3) Process to obtain a recipient specimen, if possible, for crossmatch that is collected on the day of the transplant and prior to transplantation. If the laboratory is unable to obtain a

recipient specimen on the day of the transplant, the laboratory must have a process to document its efforts to obtain the specimen.

(f) *Documentation.* The laboratory must document all control procedures performed, as specified in this section.

18. Effective December 28, 2024, amend § 493.1359 by revising paragraph (b)(2) and adding paragraphs (c) and (d) to read as follows:

§ 493.1359 Standard; PPM laboratory director responsibilities.

* * * * *

(b) * * *

(2) Is performed in accordance with applicable requirements in this subpart and subparts H, J, and K of this part;

(c) Evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(1) Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and testing;

(2) Monitoring the recording and reporting of test results;

(3) Review of test results or worksheets;

(4) Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and

(5) Assessment of problem solving skills; and

(d) Evaluate and document the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations and documentation must be performed at least annually.

19. Effective December 28, 2024, amend § 493.1405 by revising paragraph (b) to read as

follows:

§ 493.1405 Standard; Laboratory director qualifications.

* * * * *

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have had laboratory training or experience consisting of:

(A) At least 1 year directing or supervising nonwaived laboratory testing; and

(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; or

(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or

(B) Hold an earned doctoral degree; and

(*1*) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or

(*2*) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; and

(A) Be certified and continue to be certified by a board approved by HHS; and

(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or

(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or

(B)(*1*) Meet bachelor’s degree equivalency; and

(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or

(C)(*1*) Meet bachelor’s degree equivalency; and

(*2*) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and

(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and

(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1407; or

(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or

(B) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(*1*) Forty-eight (48) semester hours of medical laboratory science or medical laboratory technology courses; or

(*2*) Forty-eight (48) semester hours of science courses that include—

(*i*) Twelve (12) semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry;

(*ii*) Twelve (12) semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and

(*iii*) Twenty-four (24) semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and

(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and

(iii) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and

(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1407.

(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

§ 493.1406 [Removed]

20. Effective December 28, 2024, § 493.1406 is removed.

21. Effective December 28, 2024, amend § 493.1407 by revising paragraph (c) to read as follows:

§ 493.1407 Standard; Laboratory director responsibilities.

* * * * *

(c) The laboratory director must:

(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and

(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

* * * * *

22. Effective December 28, 2024, amend § 493.1411 by revising paragraph (b) to read as follows:

§ 493.1411 Standard; Technical consultant qualifications.

* * * * *

(b) The technical consultant must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(B) Meet either requirements in § 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); and

(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(B) Meet § 493.1405(b)(5)(i)(B); and

(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and

(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

(6) For blood gas analysis, the individual must—

(i) Be qualified under paragraph (b)(1), (2), (3), or (4) of this section; or

(ii)(A) Have earned a bachelor’s degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or

(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

Note 1 to paragraph (b): The technical consultant requirements for “laboratory training or experience, or both” in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

23. Effective December 28, 2024, amend § 493.1417 by revising paragraph (a) to read as follows:

§ 493.1417 Standard; Clinical consultant qualifications.

* * * * *

(a) Be qualified as a laboratory director under § 493.1405(b)(1), (2), or (3); or

* * * * *

24. Effective December 28, 2024, amend § 493.1423 by revising paragraph (b) to read as follows:

§ 493.1423 Standard; Testing personnel qualifications.

* * * * *

(b) Meet one of the following requirements:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or

(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or

(3) Meet the requirements in § 493.1405(b)(3)(i)(B), (b)(4)(i)(B) or (C), or (b)(5)(i)(B); or

(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or

(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(6)(i) Have earned a high school diploma or equivalent; and

(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

(F) The skills required to implement the quality control policies and procedures of the laboratory;

(G) An awareness of the factors that influence test results; and

(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

(7) For blood gas analysis, the individual must—

(i) Be qualified under paragraph (b)(1), (2), (3), or (4) of this section; or

(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(B) Have at least 1 year of laboratory training or experience, or both, in blood gas analysis; or

(iii)(A) Have earned an associate degree related to pulmonary function from an accredited institution; and

(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis.

(8) Notwithstanding any other provision of this section, an individual is considered qualified as a testing personnel under this section if they were qualified and serving as a testing personnel for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

25. Effective December 28, 2024, amend § 493.1443 by revising paragraph (b) to read as follows:

§ 493.1443 Standard: Laboratory director qualifications.

* * * * *

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 2 years of experience directing or supervising high complexity testing; and

(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445; or

(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or

(B) Hold an earned doctoral degree; and

(*1*) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or

(*2*) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(ii) Be certified and continue to be certified by a board approved by HHS; and

(iii) Have at least 2 years of:

(A) Laboratory training or experience, or both: and

(B) Laboratory experience directing or supervising high complexity testing; and

(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445; or

(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.

26. Effective December 28, 2024, amend § 493.1445 by revising paragraphs (c) and (e)(10) to read as follows:

§ 493.1445 Standard; Laboratory director responsibilities.

* * * * *

(c) The laboratory director must:

(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and

(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

* * * * *

(e) * * *

(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 493.1489(b)(5);

* * * * *

27. Effective December 28, 2024, § 493.1449 is revised to read as follows:

§ 493.1449 Standard; Technical supervisor qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor—

(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(c) Bacteriology, Mycobacteriology, Mycology, Parasitology or Virology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty; or

(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(B) Meet the requirements in § 493.1443(b)(3)(i)(B); and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or

(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(B)(*1*) Meet bachelor's degree equivalency; and

(*2*) Have at least 16 semester hours of additional graduate level coursework in chemical, biological, clinical or medical laboratory science, or medical technology; or

(C)(*1*) Meet bachelor's degree equivalency; and

(*2*) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, or clinical or medical laboratory science and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or

(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(B) Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(*1*) Forty-eight (48) semester hours of medical laboratory technology courses; or

(*2*) Forty-eight (48) semester hours of science courses that include—

(*i*) Twelve (12) semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry;

(*ii*) Twelve (12) semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and

(*iii*) Twenty-four (24) semester hours of chemistry, biology, or medical laboratory science or technology in any combination; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty.

(d) Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, or Immunohematology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or

(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(B) Meet the education requirement at § 493.1443(b)(3)(i)(B); and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the applicable specialty; or

(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(B) Meet the education requirement at paragraph (c)(4)(i)(B) or (C) of this section; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or

(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(B) Meet the education requirement at paragraph (c)(5)(i)(B) of this section; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty.

(e) Cytology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2) An individual qualified under paragraph (b) or (e)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraph (b) or (e)(1)(ii) of this section provided the technical supervisor qualified under paragraph (b) or (e)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

(f) Histopathology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must—

(1) Meet one of the following requirements:

(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) An individual qualified under paragraph (b) of this section or this paragraph (f)(1) may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.

(2) For tests in dermatopathology, meet one of the following requirements:

(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Meet one of the following requirements:

(*1*) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(*2*) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or

(*3*) Be certified in dermatology by the American Board of Dermatology; or

(ii) An individual qualified under paragraph (b) or (f)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

(3) For tests in ophthalmic pathology, meet one of the following requirements:

(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Must meet one of the following requirements:

(*1*) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(*2*) Be certified by the American Board of Ophthalmology and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or

(ii) An individual qualified under paragraph (b) or (f)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or

(g) Oral Pathology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2) Be certified in oral pathology by the American Board of Oral Pathology; or

(3) An individual qualified under paragraph (b) or (g)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (g)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(h) Histocompatibility- If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or

(2)(i) Have an earned doctoral degree in a biological, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at § 493.1443(b)(3)(i)(B); and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.

(i) Clinical cytogenetics- If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at § 493.1443(b)(3)(i)(B); and

(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

(j) Notwithstanding any other provision of this section, an individual is considered qualified as a technical supervisor under this section if they were qualified and serving as a technical supervisor for high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

Note 1 to paragraphs (b) through (i): The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year

of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

28. Effective December 28, 2024, amend § 493.1451 by revising paragraph (c) introductory text to read as follows:

§ 493.1451 Standard: Technical supervisor responsibilities.

* * * * *

(c) In cytology, the technical supervisor or the individual qualified under § 493.1449(e)(2)—

* * * * *

29. Effective December 28, 2024, amend § 493.1455 by revising paragraph (a) to read as follows:

§ 493.1455 Standard: Clinical consultant qualifications.

* * * * *

(a) Be qualified as a laboratory director under § 493.1443(b)(1), (2), or (3) or, for the subspecialty of oral pathology, § 493.1443(b)(5);

* * * * *

30. Effective December 28, 2024, amend § 493.1461 by revising paragraphs (c), (d)(3)(i), and (e) to read as follows:

§ 493.1461 Standard: General supervisor qualifications.

* * * * *

(c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(2)(i) Qualify as testing personnel under § 493.1489(b)(3); and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(3) Meet the requirements at § 493.1443(b)(3) or § 493.1449(c)(4) or (5); or

(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

(d) * * *

(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and

* * * * *

(e) * * *

(1) In histopathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (f)(1);

(2) In dermatopathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (f)(2);

(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (f)(3); and

(4) In oral pathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (g).

§ 493.1462 [Removed]

31. Effective December 28, 2024, § 493.1462 is removed.

32. Effective December 28, 2024, amend § 493.1463 by revising paragraph (b)(4) to read as follows:

§ 493.1463 Standard: General supervisor responsibilities.

* * * * *

(b) * * *

(4) Evaluating and documenting the competency of all testing personnel.

* * * * *

33. Effective December 28, 2024, amend § 493.1469 by revising paragraph (a) to read as follows:

§ 493.1469 Standard: Cytology general supervisor qualifications.

* * * * *

(a) Be qualified as a technical supervisor under § 493.1449(b) or (e); or

* * * * *

34. Amend § 493.1483 by revising the introductory text and paragraph (b) to read as follows:

§ 493.1483 Standard: Cytotechnologist qualifications.

Each person examining cytology slide preparations must meet the qualifications of § 493.1449 (b) or (e), or—

* * * * *

(b) Meet one of the following requirements:

(1) Have graduated from a school of cytotechnology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or

(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(3) Notwithstanding any other provision of this section, an individual is considered qualified as a cytotechnologist under this section if they were qualified and serving as a cytotechnologist in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since December 28, 2024.

35. Effective December 28, 2024, amend § 493.1489 by revising paragraph (b) to read as follows:

§ 493.1489 Standard; Testing personnel qualifications.

* * * * *

(b) Meet one of the following requirements:

(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or

(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution;

(ii) Be qualified under the requirements of § 493.1443(b)(3) or § 493.1449(c)(4) or (5); or

(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or—

(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(*1*) Twenty-four (24) semester hours of medical laboratory technology courses; or

(*2*) Twenty-four (24) semester hours of science courses that include—

(*i*) Six (6) semester hours of chemistry;

(*ii*) Six (6) semester hours of biology; and

(*iii*) Twelve (12) semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(B) Have laboratory training that includes:

(*1*) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or

(*2*) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or

(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

(6) For blood gas analysis—

(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or

(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(iii) Have earned an associate degree related to pulmonary function from an accredited institution.

(7) For histopathology, meet the qualifications of § 493.1449(b) or (f) to perform tissue examinations.

§ 493.1491 [Removed]

36. Effective December 28, 2024, § 493.1491 is removed.

37. Effective December 28, 2024, amend § 493.1804 by revising paragraph (c)(1) to read as follows:

§ 493.1804 General considerations.

* * * * *

(c) * * *

(1) CMS may impose alternative sanctions in lieu of, or in addition to, principal sanctions.

* * * * *

_____

Xavier Becerra,

Secretary,

Department of Health and Human Services.

[FR Doc. 2023-28170 Filed: 12/22/2023 4:15 pm; Publication Date: 12/28/2023]